

30-1 ROUTINE COSTS IN CLINICAL TRIALS

Effective for items and services furnished on or after September 19, 2000, Medicare covers the routine costs of qualifying clinical trials, as such costs are defined below, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply.

Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national noncoverage decision) that are provided in either the experimental or the control arms of a clinical trial except:

- o The investigational item or service, itself;
- o Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and
- o Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.

Routine costs in clinical trials include:

- o Items or services that are typically provided absent a clinical trial (e.g., conventional care);
- o Items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
- o Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service--in particular, for the diagnosis or treatment of complications.

This policy does not withdraw Medicare coverage for items and services that may be covered according to local medical review policies or the regulations on category B investigational device exemptions (IDE) found in 42 CFR 405.201-405.215, 411.15, and 411.406. For information about LMRPs, refer to www.lmrp.net, a searchable database of Medicare contractors' local policies.

For noncovered items and services, including items and services for which Medicare payment is statutorily prohibited, Medicare only covers the treatment of complications arising from the delivery of the noncovered item or service and unrelated reasonable and necessary care. (Refer to MCM §§2300.1 and MIM 3101.) However, if the item or service is not covered by virtue of a national noncoverage policy in the Coverage Issues Manual and is the focus of a qualifying clinical trial, the routine costs of the clinical trial (as defined above) will be covered by Medicare but the noncovered item or service, itself, will not.

A. Requirements for Medicare Coverage of Routine Costs.--Any clinical trial receiving Medicare coverage of routine costs must meet the following three requirements:

1. The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians' service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).

2. The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent.

3. Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.

The three requirements above are insufficient by themselves to qualify a clinical trial for Medicare coverage of routine costs. Clinical trials also should have the following desirable characteristics; however, some trials, as described below, are presumed to meet these characteristics and are automatically qualified to receive Medicare coverage:

1. The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes;

2. The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use;

3. The trial does not unjustifiably duplicate existing studies;

4. The trial design is appropriate to answer the research question being asked in the trial;

5. The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully;

6. The trial is in compliance with Federal regulations relating to the protection of human subjects; and

7. All aspects of the trial are conducted according to the appropriate standards of scientific integrity.

B. Qualification Process for Clinical Trials.--Using the authority found in §1142 of the Act (cross-referenced in §1862(a)(1)(E) of the Act), the Agency for Healthcare Research and Quality (AHRQ) will convene a multi-agency Federal panel (the "panel") composed of representatives of the Department of Health and Human Services research agencies (National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), AHRQ, and the Office of Human Research Protection), and the research arms of the Department of Defense (DOD) and the Department of Veterans Affairs (VA) to develop qualifying criteria that will indicate a strong probability that a trial exhibits the desirable characteristics listed above. These criteria will be easily verifiable, and where possible, dichotomous. Trials that meet these qualifying criteria will receive Medicare coverage of their associated routine costs. This panel is not reviewing or approving individual trials. The multi-agency panel will meet periodically to review and evaluate the program and recommend any necessary refinements to HCFA.

Clinical trials that meet the qualifying criteria will receive Medicare coverage of routine costs after the trial's lead principal investigator certifies that the trial meets the criteria. This process will require the principal investigator to enroll the trial in a Medicare clinical trials registry, currently under development.

Some clinical trials are automatically qualified to receive Medicare coverage of their routine costs because they have been deemed by AHRQ, in consultation with the other agencies represented on the multi-agency panel to be highly likely to have the above-listed seven desirable characteristics of clinical trials. The principal investigators of these automatically qualified trials do not need to certify that the trials meet the qualifying criteria, but must enroll the trials in the Medicare clinical trials registry for administrative purposes, once the registry is established.

Effective September 19, 2000, clinical trials that are deemed to be automatically qualified are:

1. Trials funded by NIH, CDC, AHRQ, HCFA, DOD, and VA;
2. Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, HCFA, DOD and VA;
3. Trials conducted under an investigational new drug application (IND) reviewed by the FDA; and
4. Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1) will be deemed automatically qualified until the qualifying criteria are developed and the certification process is in place. At that time the principal investigators of these trials must certify that the trials meet the qualifying criteria in order to maintain Medicare coverage of routine costs. This certification process will only affect the future status of the trial and will not be used to retroactively change the earlier deemed status.

Medicare will cover the routine costs of qualifying trials that either have been deemed to be automatically qualified or have certified that they meet the qualifying criteria unless HCFA's Chief Clinical Officer subsequently finds that a clinical trial does not meet the qualifying criteria or jeopardizes the safety or welfare of Medicare beneficiaries.

Should HCFA find that a trial's principal investigator misrepresented that the trial met the necessary qualifying criteria in order to gain Medicare coverage of routine costs, Medicare coverage of the routine costs would be denied under §1862(a)(1)(E) of the Act. In the case of such a denial, the Medicare beneficiaries enrolled in the trial would not be held liable (i.e., would be held harmless from collection) for the costs consistent with the provisions of §§1879, 1842(l), or 1834(j)(4) of the Act, as applicable. Where appropriate, the billing providers would be held liable for the costs and fraud investigations of the billing providers and the trial's principal investigator may be pursued.

Medicare regulations require Medicare+Choice (M+C) organizations to follow HCFA's national coverage decisions. This NCD raises special issues that require some modification of most M+C organizations' rules governing provision of items and services in and out of network. The items and services covered under this NCD are inextricably linked to the clinical trials with which they are associated and cannot be covered outside of the context of those clinical trials. M+C organizations therefore must cover these services regardless of whether they are available through in-network providers. M+C organizations may have reporting requirements when enrollees participate in clinical trials, in order to track and coordinate their members' care, but cannot require prior authorization or approval.

35 MEDICAL PROCEDURES

35-1 COLONIC IRRIGATION--NOT COVERED

Colonic irrigation is a procedure to wash out or lavage material on the walls of the bowel to an unlimited distance without inducing defecation. This procedure is distinguished from all types of enemas which are primarily used to induce defecation.

There are no conditions for which colonic irrigation is medically indicated and no evidence of therapeutic value. Accordingly, colonic irrigation cannot be considered reasonable and necessary within the meaning of section 1862(a)(1) of the law.

35-2 MANIPULATION

- A. Manipulation of the Rib Cage.--Manual manipulation of the rib cage contributes to the treatment of respiratory conditions such as bronchitis, emphysema, and asthma as part of a regimen which includes other elements of therapy, and is covered only under such circumstances.
- B. Manipulation of the Head.--Manipulation of the occipitocervical or temporomandibular regions of the head when indicated for conditions affecting those portions of the head and neck is a covered service.

35-3 HEAT TREATMENT, INCLUDING THE USE OF DIATHERMY AND ULTRASOUND FOR PULMONARY CONDITIONS--NOT COVERED

There is no physiological rationale or valid scientific documentation of effectiveness of diathermy or ultrasound heat treatments for asthma, bronchitis, or any other pulmonary condition and for such purpose this treatment cannot be considered reasonable and necessary within the meaning of section 1862(a)(1) of the law.

Cross-refer: §35-41

35-4 ULTRASONIC SURGERY

Reimbursement may be made for ultrasonic surgery when required in the treatment of patients with severe and recurrent episodes of vertigo due to Meniere's syndrome.

This procedure utilizes a machine which produces ultrasonic waves of high intensity and frequency that selectively irradiate certain portions of the inner ear thereby destroying the tissue. The procedure is usually done under local anesthesia, and requires the services of a surgeon and another individual who is responsible for calibrating the electrical equipment, and who assists in observing certain physical changes (e.g., movement of the eyes, "nystagmus") indicative of inner ear reaction to the ultrasonic destruction. Except in rare instances the desired result is achieved with one treatment. At present, there are two different approaches being used to apply the ultrasound to the inner ear: one through the lateral semicircular canal and, more recently, a simpler approach from a technical viewpoint, through the round window.

35-5 CELLULAR THERAPY--NOT COVERED

Cellular therapy involves the practice of injecting humans with foreign proteins like the placenta or lungs of unborn lambs. Cellular therapy is without scientific or statistical evidence to document its therapeutic efficacy and, in fact, is considered a potentially dangerous practice. Accordingly, cellular therapy is not considered reasonable and necessary within the meaning of section 1862 (a) (1) of the law.

35-6 THERMOGENIC THERAPY--NOT COVERED

Thermogenic therapy which is the production of artificial fever has been in use since 1919 in the treatment of certain types of resistant infectious diseases, rheumatoid arthritis and Sydenham's chorea. Regardless of the medium by which the fever is induced, this modality is not scientifically accepted for the treatment of any specific disease. Since the advent of potent antibiotics, the procedure has for all practical purposes been replaced as a mode of treatment. Therefore, thermogenic therapy is not considered reasonable and necessary for the treatment of an illness or injury as required by section 1862(a)(1) of the law. (Of course, where other covered services are needed and it would be reasonable and necessary that they be furnished on an inpatient hospital basis, payment would not be excluded for the inpatient stay, notwithstanding the fact that reimbursement may not be made for thermogenic therapy furnished during the hospital stay.)

35-7 CAROTID BODY RESECTION/CAROTID BODY DENERVATION

Carotid body resection is occasionally used to relieve pulmonary symptoms, including asthma, but has been shown to lack general acceptance of the professional medical community. In addition, controlled clinical studies establishing the safety and effectiveness of this procedure are needed. Therefore, all carotid body resections to relieve pulmonary symptoms must be considered investigational and cannot be considered reasonable and necessary within the meaning of section 1862(a)(1) of the law. No program reimbursement may be made in such cases.

There is, however, one instance where carotid body resection has been accepted by the medical community as effective. That instance is when evidence of a mass in the carotid body, with or without symptoms, indicates the need for surgery to remove the carotid body tumor.

Denervation of a carotid sinus to treat hypersensitive carotid sinus reflex is another procedure performed in the area of the carotid body. In the case of hypersensitive carotid sinus, light pressure on the upper part of the neck (such as might be experienced when turning or raising one's head) results in symptoms such as dizziness or syncope due to hypotension and slowed heart rate. Failure of medical therapy and continued deterioration in the condition of the patient in such cases may indicate need for surgery. Denervation of the carotid sinus is rarely performed, but when elected as the therapy of choice with the above indications, this procedure may be considered reasonable and necessary.

35-8 ACUPUNCTURE--NOT COVERED

Although acupuncture has been used for thousands of years in China and for decades in parts of Europe, it is a new agent of unknown use and efficacy in the United States. Even

in those areas of the world where it has been widely used, its mechanism is not known. Three units of the National Institutes of Health, the National Institute of General Medical Sciences, National Institute of Neurological Diseases and Stroke, and Fogarty International Center have been designed to assess and identify specific opportunities and needs for research attending the use of acupuncture for surgical anesthesia and relief of chronic pain. Until the pending scientific assessment of the technique has been completed and its efficacy has been established, Medicare reimbursement for acupuncture, as an anesthetic or as an analgesic or for other therapeutic purposes, may not be made. Accordingly, acupuncture is not considered reasonable and necessary within the meaning of §1862(a)(1) of the Act.

35-9 PHACO-EMULSIFICATION PROCEDURE - CATARACT EXTRACTION

In view of recommendations of authoritative sources in the field of ophthalmology, the subject technique is viewed as an accepted procedure for removal of cataracts. Accordingly, program reimbursement may be made for necessary services furnished in connection with cataract extraction utilizing the phaco-emulsification procedure.

35-10 HYPERBARIC OXYGEN THERAPY

For purposes of coverage under Medicare, hyperbaric oxygen (HBO) therapy is a modality in which the entire body is exposed to oxygen under increased atmospheric pressure.

A. Covered Conditions.--Program reimbursement for HBO therapy will be limited to that which is administered in a chamber (including the one man unit) and is limited to the following conditions:

1. Acute carbon monoxide intoxication, (ICD-9 -CM diagnosis 986).
2. Decompression illness, (ICD-9-CM diagnosis 993.2, 993.3).
3. Gas embolism, (ICD-9-CM diagnosis 958.0, 999.1).
4. Gas gangrene, (ICD-9-CM diagnosis 0400).
5. Acute traumatic peripheral ischemia. HBO therapy is a valuable adjunctive treatment to be used in combination with accepted standard therapeutic measures when loss of function, limb, or life is threatened. (ICD-9-CM diagnosis 902.53, 903.01, 903.1, 904.0, 904.41.)
6. Crush injuries and suturing of severed limbs. As in the previous conditions, HBO therapy would be an adjunctive treatment when loss of function, limb, or life is threatened. (ICD-9-CM diagnosis 927.00- 927.03, 927.09-927.11, 927.20-927.21, 927.8-927.9, 928.00-928.01, 928.10-928.11, 928.20-928.21, 928.3, 928.8-928.9, 929.0, 929.9, 996.90- 996.99.)
7. Progressive necrotizing infections (necrotizing fasciitis), (ICD-9-CM diagnosis 728.86).
8. Acute peripheral arterial insufficiency, (ICD-9-CM diagnosis 444.21, 444.22, 444.81).
9. Preparation and preservation of compromised skin grafts (not for primary management of wounds), (ICD-9CM diagnosis 996.52; excludes artificial skin graft).
10. Chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management, (ICD-9-CM diagnosis 730.10-730.19).

11. Osteoradionecrosis as an adjunct to conventional treatment, (ICD-9-CM diagnosis 526.89).
12. Soft tissue radionecrosis as an adjunct to conventional treatment, (ICD-9-CM diagnosis 990).
13. Cyanide poisoning, (ICD-9-CM diagnosis 987.7, 989.0).
14. Actinomycosis, only as an adjunct to conventional therapy when the disease process is refractory to antibiotics and surgical treatment, (ICD-9-CM diagnosis 039.0-039.4, 039.8, 039.9).

B. Noncovered Conditions.--All other indications not specified under §35-10 (A) are not covered under the Medicare program. No program payment may be made for any conditions other than those listed in §35-10(A).

No program payment may be made for HBO in the treatment of the following conditions:

1. Cutaneous, decubitus, and stasis ulcers.
2. Chronic peripheral vascular insufficiency.
3. Anaerobic septicemia and infection other than clostridial.
4. Skin burns (thermal).
5. Senility.
6. Myocardial infarction.
7. Cardiogenic shock..
8. Sick cell anemia.
9. Acute thermal and chemical pulmonary damage, i.e., smoke inhalation with pulmonary insufficiency.
10. Acute or chronic cerebral vascular insufficiency.
11. Hepatic necrosis.
12. Aerobic septicemia.
13. Nonvascular causes of chronic brain syndrome (Pick's disease, Alzheimer's disease, Korsakoff's disease).
14. Tetanus.
15. Systemic aerobic infection.
16. Organ transplantation.
17. Organ storage.
18. Pulmonary emphysema.
19. Exceptional blood loss anemia.
20. Multiple Sclerosis.
21. Arthritic Diseases.
22. Acute cerebral edema.

C. Reasonable Utilization Parameters.--Make payment where HBO therapy is clinically practical. HBO therapy should not be a replacement for other standard successful therapeutic measures. Depending on the response of the individual patient and the severity of the original problem, treatment may range from less than 1 week to several months duration, the average being 2 to 4 weeks. Review and document the medical necessity for use of hyperbaric oxygen for more than 2 months, regardless of the condition of the patient, before further reimbursement is made.

D. Topical Application of Oxygen.--This method of administering oxygen does not meet the definition of HBO therapy as stated above. Also, its clinical efficacy has not been established. Therefore, no Medicare reimbursement may be made for the topical application of oxygen. (Cross refer: §35-31.)

35-11 STERILIZATION

A. Covered Conditions--

- o Payment may be made only where sterilization is a necessary part of the treatment of an illness or injury, e.g., removal of a uterus because of a tumor, removal of diseased ovaries

- o Sterilization of a mentally retarded beneficiary is covered if it is a necessary part of the treatment of an illness or injury. (bilateral oophorectomy), or bilateral orchidectomy in a case of cancer of the prostate. Deny claims when the pathological evidence of the necessity to perform any such procedures to treat an illness or injury is absent; and .

Monitor such surgeries closely and obtain the information needed to determine whether in fact the surgery was performed as a means of treating an illness or injury or only to achieve sterilization.

B. Noncovered Conditions--

- o Elective hysterectomy, tubal ligation, and vasectomy, if the stated reason for these procedures is sterilization;

- o A sterilization that is performed because a physician believes another pregnancy would endanger the overall general health of the woman is not considered to be reasonable and necessary for the diagnosis or treatment of illness or injury within the meaning of §1862(a)(1) of the law. The same conclusion would apply where the sterilization is performed only as a measure to prevent the possible development of, or effect on, a mental condition should the individual become pregnant; and

- o Sterilization of a mentally retarded person where the purpose is to prevent conception, rather than the treatment of an illness or injury.

35-12 PLASTIC SURGERY TO CORRECT "MOON FACE"--NOT COVERED

The cosmetic surgery exclusion precludes payment for any surgical procedure directed at improving appearance. The condition giving rise to the patient's preoperative appearance is generally not a consideration. The only exception to the exclusion is surgery for the prompt repair of an accidental injury or for the improvement of a malformed body member which coincidentally serves some cosmetic purpose. Since surgery to correct a condition of "moon face" which developed as a side effect of cortisone therapy does not meet the exception to the exclusion, it is not covered under Medicare (§1862(a)(10) of the Act).

Cross refer: Intermediary Manual, §3160; Carriers Manual, §2329; Hospital Manual, §260.11.

35-13 PROLOTHERAPY, JOINT SCLEROTHERAPY, AND LIGAMENTOUS INJECTIONS WITH SCLEROSING AGENTS--NOT COVERED

The medical effectiveness of the above therapies has not been verified by scientifically controlled studies. Accordingly, reimbursement for these modalities should be denied on the ground that they are not reasonable and necessary as required by §1862(a)(1) of the law.

35-14 CONSULTATIONS WITH A BENEFICIARY'S FAMILY AND ASSOCIATES

In certain types of medical conditions, including when a patient is withdrawn and uncommunicative due to a mental disorder or comatose, the physician may contact relatives and close associates to secure background information to assist in diagnosis and treatment planning. When a physician contacts his patient's relatives or associates for this purpose, expenses of such interviews are properly chargeable as physician's services to the patient on whose behalf the information was secured. If the beneficiary is not an inpatient of a hospital, Part B reimbursement for such an interview is subject to the special limitation on payments for physicians' services in connection with mental, psychoneurotic, and personality disorders.

A physician may also have contacts with a patient's family and associates for purposes other than securing background information. In some cases, the physician will provide counseling to members of the household. Family counseling services are covered only where the primary purpose of such counseling is the treatment of the patient's condition. For example, two situations where family counseling services would be appropriate are as follows: (1) where there is a need to observe the patient's interaction with family members; and/or (2) where there is a need to assess the capability of and assist the family members in aiding in the management of the patient. Counseling principally concerned with the effects of the patient's condition on the individual being interviewed would not be reimbursable as part of the physician's personal services to the patient. While to a limited degree, the counseling described in the second situation may be used to modify the behavior of the family members, such services nevertheless are covered because they relate primarily to the management of the patient's problems and not to the treatment of the family member's problems.

See Medicare Intermediary Manual, §3212; Medicare Carriers Manual, §§2020 and 2470-2476.2; and Hospital Manual, §160.1.

35-15 POSTURAL DRAINAGE PROCEDURES AND PULMONARY EXERCISES

In most cases, postural drainage procedures and pulmonary exercises can be carried out safely and effectively by nursing personnel. However, in some cases patients may have acute or severe pulmonary conditions involving complex situations in which these procedures or exercises require the knowledge and skills of a physical therapist or a respiratory therapist. Therefore, if the attending physician determines as part of his/her plan of treatment that for the safe and effective administration of such services the procedures or exercises in question need to be performed by a physical therapist, the services of such a therapist constitute covered physical therapy when provided as an inpatient hospital service, extended care service, home health service, or outpatient physical therapy service.

NOTE: Physical therapy furnished in the outpatient department of a hospital is covered under the outpatient physical therapy benefit.

If the attending physician determines that the services should be performed by a respiratory therapist, the services of such a therapist constitute covered respiratory therapy when provided as an inpatient hospital service, outpatient hospital service, or extended care service, assuming that such services are furnished to the skilled nursing facility by a hospital with which the facility has a transfer agreement. Since the services of a respiratory therapist are not covered under the home health benefit, payment may not be made under the home health benefit for visits by a respiratory therapist to a patient's home to provide such services. Postural drainage procedures and pulmonary exercises are also covered when furnished by a physical therapist or a respiratory therapist as incident to a physician's professional service.

See Medicare Intermediary Manual, §§3112, §3116, and §3133.90 and Medicare Carriers Manual, §2050.2.

35-16 VITRECTOMY

Vitrectomy may be considered reasonable and necessary for the following conditions: vitreous loss incident to cataract surgery, vitreous opacities due to vitreous hemorrhage or other causes, retinal detachments secondary to vitreous strands, proliferative retinopathy, and vitreous retraction. See chapter 15 of the Medicare Carriers Manual for how to determine payment for physician vitrectomy services and §5243 of the Medicare Carriers Manual for how to determine payment for ASC facility vitrectomy services. Also, see §4630 of the Medicare Carriers Manual to identify when, for Medicare payment purposes, certain vitrectomy codes are included in other codes or when codes for other services include vitrectomy codes. The CPT codes for vitrectomy services are 67005, 67010, 67036, 67038, 67039, and 67040.

35-17 INDUCED LESIONS OF NERVE TRACTS

Surgically induced lesions of nerve tracts, which involve destruction of nerve tissue, are primarily indicated for controlling the chronic or acute pain arising from conditions such as terminal cancer or lumbar degenerative arthritis. Induced lesions of nerve tracts may be produced by surgical cutting of the nerve (rhizolysis), chemical destruction of the nerve, or by creation of a radio-frequency lesion (electrocautery). Accordingly, program payment may be made for these denervation procedures when used in selected cases (concurred in by contractor's medical staff) to treat chronic pain.

Note that these procedures differ from those employing implanted electrodes and associated equipment to control pain in that the nerve fibers are ablated rather than stimulated and no electronic equipment is required by the patient after the operation.

35-18 ELECTROSLEEP THERAPY--NOT COVERED

Electrosleep therapy consists of the application of short duration, low-amplitude pulses of direct current to the patient's brain via externally placed occipital electrodes. It is commonly used in the treatment of chronic insomnia, anxiety, and depression, but has also been used for psychosomatic disorders such as asthma, spastic colitis, or tension headache, and for organic disorders including essential hypertension. Until scientific assessment of this technique has been completed and its efficacy is established, no program payment may be made for electrosleep therapy.

35-19 INTRAVENOUS HISTAMINE THERAPY

The only accepted and scientifically valid medical use of histamine is diagnostic, including tests to assess:

- o The ability of the stomach to secrete acid;
- o The integrity of peripheral sensory nerves (e.g., in leprosy);
- o The circulatory competency in limb extremities; and
- o The presence of a pheochromocytoma.

However, there is no scientifically valid clinical evidence that histamine therapy is effective for any condition regardless of the method of administration, nor is it accepted or widely used by the medical profession. Therefore, histamine therapy cannot be considered reasonable and necessary, and program payment for such therapy is not made.

35-20 TREATMENT OF MOTOR FUNCTION DISORDERS WITH ELECTRIC NERVE STIMULATION--NOT COVERED

While electric nerve stimulation has been employed to control chronic intractable pain for some time, its use in the treatment of motor function disorders, such as multiple sclerosis, is a recent innovation, and the medical effectiveness of such therapy has not been verified by scientifically controlled studies. Therefore, where electric nerve stimulation is employed to treat motor function disorders, no reimbursement may be made for the stimulator or for the services related to its implantation since this treatment cannot be considered reasonable and necessary.

See §§35-27 and 65-8.

NOTE: Medicare coverage of deep brain stimulation by implantation of a stimulator device is not prohibited. Therefore, coverage of deep brain stimulation provided by an implanted deep brain stimulator is at the carrier's discretion.

35-21 INPATIENT HOSPITAL PAIN REHABILITATION PROGRAMS

Pain rehabilitation programs are a relatively new and innovative approach to the treatment of intractable pain. The goal of such programs is to give a patient the tools to manage and control his/her pain and thereby improve his/her ability to function independently.

A hospital level pain rehabilitation program is one that employs a coordinated multidisciplinary team to deliver, in a controlled environment, a concentrated program which is designed to modify pain behavior through the treatment of the physiological, psychological, and social aspects of pain. Such programs generally include diagnostic testing, skilled nursing, psychotherapy, structured progressive withdrawal from pain medications, physical therapy and occupational therapy to restore physical fitness (mobility and endurance) to a

maximal level within the constraints of a patient's physical disability, and the use of mechanical devices and/or activities to relieve pain or modify a patient's reaction to it (e.g., nerve stimulator, hydrotherapy, massage, ice, systemic muscle relaxation training, and diversional activities). The nurse's responsibility in such pain rehabilitation programs is to observe and assess, on a continuing basis, a patient's condition and response to the program as reflected by his actions while in the nursing unit, and to assure that the atmosphere within the unit is not supportive of pain behavior. The day-to-day activities involved in carrying out the program are under the general supervision and, as needed, direct supervision of a physician.

Since pain rehabilitation programs of a lesser scope than that described above would raise a question as to whether the program could be provided in a less intensive setting than on an inpatient hospital basis, carefully evaluate such programs to determine whether the program does, in fact, necessitate a hospital level of care. Some pain rehabilitation programs may utilize services and devices which are excluded from coverage, e.g., acupuncture (see §35-8), biofeedback (see §35-27), dorsal column stimulator (see §65-8), and family counseling services (see §35-14). In determining whether the scope of a pain program does necessitate inpatient hospital care, evaluate only those services and devices which are covered. Although diagnostic tests may be an appropriate part of pain rehabilitation programs, such tests would be covered in an individual case only where they can be reasonably related to a patient's illness, complaint, symptom, or injury and where they do not represent an unnecessary duplication of tests previously performed.

An inpatient program of 4 week's duration is generally required to modify pain behavior. After this period it would be expected that any additional rehabilitation services which might be required could be effectively provided on an outpatient basis under an outpatient pain rehabilitation program (see §35-21.1sf2) or other outpatient program. The first 7-10 days of such an inpatient program constitute, in effect, an evaluation period. If a patient is unable to adjust to the program within this period, it is generally concluded that it is unlikely that the program will be effective and the patient is discharged from the program. On occasions a program longer than 4 weeks may be required in a particular case. In such a case there should be documentation to substantiate that inpatient care beyond a 4-week period was reasonable and necessary. Similarly, where it appears that a patient participating in a program is being granted frequent outside passes, a question would exist as to whether an inpatient program is reasonable and necessary for the treatment of the patient's condition.

An inpatient hospital stay for the purpose of participating in a pain rehabilitation program would be covered as reasonable and necessary to the treatment of a patient's condition where the pain is attributable to a physical cause, the usual methods of treatment have not been successful in alleviating it, and a significant loss of ability to function independently has resulted from the pain. Chronic pain patients often have psychological problems which accompany or stem from the physical pain and it is appropriate to include psychological treatment in the multidisciplinary approach. However, patients whose pain symptoms result from a mental condition, rather than from any physical cause, generally cannot be successfully treated in a pain rehabilitation program.

35-21.1 OUTPATIENT HOSPITAL PAIN REHABILITATION PROGRAMS

Some hospitals also provide pain rehabilitation programs for outpatients. In such programs, services frequently are provided in group settings even though they are being furnished pursuant to each patient's individualized plan of treatment.

Coverage of services furnished under outpatient hospital pain rehabilitation programs, including services furnished in group settings under individualized plans of treatment, is available if the patient's pain is attributable to a physical cause, the usual methods of treatment have not been successful in alleviating it, and a significant loss of ability by the patient to function independently has resulted from the pain. If a patient meets these conditions and the program provides services of the types discussed in §35-21 the services provided under the program may be covered. Noncovered services (e.g., vocational counseling, meals for outpatients, or acupuncture) continue to be excluded from coverage, and intermediaries would not be precluded from finding, in the case of particular patients, that the pain rehabilitation program is not reasonable and necessary under §1862(a)(1) of the law for the treatment of their conditions.

35-22 INPATIENT HOSPITAL STAYS FOR THE TREATMENT OF ALCOHOLISM

A. Inpatient Hospital Stay for Alcohol Detoxification--Many hospitals provide detoxification services during the more acute stages of alcoholism or alcohol withdrawal. When the high probability or occurrence of medical complications (e.g., delirium, confusion, trauma, or unconsciousness) during detoxification for acute alcoholism or alcohol withdrawal necessitates the constant availability of physicians and/or complex medical equipment found only in the hospital setting, inpatient hospital care during this period is considered reasonable and necessary and is therefore covered under the program. Generally, detoxification can be accomplished within 2-3 days with an occasional need for up to 5 days where the patient's condition dictates. This limit (5 days) may be extended in an individual case where there is a need for a longer period for detoxification for a particular patient. In such cases, however, there should be documentation by a physician which substantiates that a longer period of detoxification was reasonable and necessary. When the detoxification needs of an individual no longer require an inpatient hospital setting, coverage should be denied on the basis that inpatient hospital care is not reasonable and necessary as required by section 1862(a)(1) of the law. Following detoxification a patient may be transferred to an inpatient rehabilitation unit or discharged to a residential treatment program or outpatient treatment setting.

B. Inpatient Hospital Stay for Alcohol Rehabilitation--Hospitals may also provide structured inpatient alcohol rehabilitation programs to the chronic alcoholic. These programs are composed primarily of coordinated educational and psychotherapeutic services provided on a group basis. Depending on the subject matter, a series of lectures, discussions, films, and group therapy sessions are led by either physicians, psychologists, or alcoholism counselors from the hospital or various outside organizations. In addition, individual psychotherapy and family counseling (see § 35-14) may be provided in selected cases. These programs are conducted under the supervision and direction of a physician. Patients may directly enter an inpatient hospital rehabilitation program after having undergone detoxification in the same hospital or in another hospital or may enter an inpatient hospital rehabilitation program without prior hospitalization for detoxification.

Alcohol rehabilitation can be provided in a variety of settings other than the hospital setting. In order for an inpatient hospital stay for alcohol rehabilitation to be covered under Medicare it must be medically necessary for the care to be provided in the inpatient hospital setting rather than in a less costly facility or on an outpatient basis. Inpatient hospital care for receipt of an alcohol rehabilitation program would generally be medically necessary where either (1) there is documentation by the physician that recent alcohol rehabilitation services in a less intensive setting or on an outpatient basis have proven unsuccessful and, as a consequence, the patient requires the supervision and intensity of services which can only be found in the controlled environment of the hospital, or (2) only the hospital environment can assure the medical management or control of the patient's concomitant conditions during the course of alcohol rehabilitation. (However, a patient's concomitant condition may make the use of certain alcohol treatment modalities medically inappropriate.) In addition, the "active treatment" criteria (see HCFA-Pub. 13-3, § 3102.1 or HCFA-Pub. 10, § 212.1) should be applied to psychiatric care in the general hospital as well as to psychiatric care in a psychiatric hospital. Since alcoholism is classifiable as a psychiatric condition the "active treatment" criteria must also be met in order for alcohol rehabilitation services to be covered under Medicare. (Thus, it is the combined need for "active treatment" and for covered care which can only be provided in the inpatient hospital setting, rather than the fact that rehabilitation immediately follows a period of detoxification, which provides the basis for coverage of inpatient hospital alcohol rehabilitation programs.)

Generally 16-19 days of rehabilitation services are sufficient to bring a patient to a point where care could be continued in other than an inpatient hospital setting. An inpatient hospital stay for alcohol rehabilitation may be extended beyond this limit in an individual case where a longer period of alcohol rehabilitation is medically necessary. In such cases, however, there should be documentation by a physician which substantiates the need for such care. Where the rehabilitation needs of an individual no longer require an inpatient hospital setting, coverage should be denied on the basis that inpatient hospital care is not reasonable and necessary as required by section 1862 (a)(1) of the law.

Subsequent admissions to the inpatient hospital setting for alcohol rehabilitation followup, reinforcement, or "recap" treatments are considered to be readmissions (rather than an extension of the original stay) and must meet the requirements of this section for coverage under Medicare. Prior admissions to the inpatient hospital setting--either in the same hospital or in a different hospital--may be an indication that the "active treatment" requirements are not met (i.e., there is no reasonable expectation of improvement) and the stay should not be covered. Accordingly, there should be documentation to establish that "readmission" to the hospital setting for alcohol rehabilitation services can reasonably be expected to result in improvement of the patient's condition. For example, the documentation should indicate what changes in the patient's medical condition, social or emotional status, or treatment plan make improvement likely, or why the patient's initial hospital treatment was not sufficient.

C. Combined Alcohol Detoxification/Rehabilitation Programs--Fiscal intermediaries should apply the guidelines in A. and B. above to both phases of a combined inpatient hospital alcohol detoxification/rehabilitation program. Not all patients who require the inpatient hospital setting for detoxification also need the inpatient hospital setting for rehabilitation. (See § 35-22.1 for coverage of outpatient hospital alcohol rehabilitation services.) Where the inpatient hospital setting is medically necessary for both alcohol detoxification and rehabilitation, generally a 3-week period is reasonable and necessary to bring the patient to the point where care can be continued in other than an inpatient hospital setting.

Decisions regarding reasonableness and necessity of treatment, the need for an inpatient hospital level of care, and length of treatment should be made by intermediaries based on accepted medical practice with the advice of their medical consultant. (In hospitals under PSRO review, PSRO determinations of medical necessity of services and appropriateness of the level of care at which services are provided are binding on the title XVIII fiscal intermediaries for purposes of adjudicating claims for payment.)

35-22.1 OUTPATIENT HOSPITAL SERVICES FOR TREATMENT OF ALCOHOLISM

Some hospitals also provide services on an outpatient basis, either individually or as part of a day hospitalization program, for treatment of alcoholism. These services may include, for example, drug therapy, psychotherapy, and patient education and may be furnished by physicians, psychologists, nurses, and alcoholism counselors to individuals who have been discharged from an inpatient hospital stay for treatment of alcoholism and require continued treatment or to individuals from the community who require treatment but do not require the inpatient hospital setting.

Coverage is available for both diagnostic and therapeutic services furnished for the treatment of alcoholism by the hospital to outpatients subject to the same rules applicable to outpatient hospital services in general (see HCFA-Pub. 13-3, §§3112 ff.; HCFA-Pub. 10, §§230 ff.). While there is no coverage for day hospitalization programs, per se, individual services which meet the requirements in HCFA-Pub. 13-3, §§3112 ff. or HCFA-Pub. 10, §§230 ff. may be covered. (Meals, transportation and recreational and social activities do not fall within the scope of covered outpatient hospital services under Medicare.)

All services must be reasonable and necessary for diagnosis or treatment of the patient's condition (see HCFA-Pub. 13-3, §3151; HCFA-Pub. 10, §260.1). Thus, educational services and family counseling would only be covered where they are directly related to treatment of the patient's condition. (See also §35-14.) The frequency of treatment and period of time over which it occurs must also be reasonable and necessary.

35-22.2 TREATMENT OF DRUG ABUSE (CHEMICAL DEPENDENCY)

We recognize that there are similarities between the approach to treatment of drug abuse and alcohol detoxification and rehabilitation. However, the intensity and duration of treatment for drug abuse may vary (depending on the particular substance(s) of abuse, duration of use, and the patient's medical and emotional condition) from the duration of treatment or intensity needed to treat alcoholism. Accordingly, when it is medically necessary for a patient to receive detoxification and/or rehabilitation for drug substance abuse as a hospital inpatient, coverage for care in that setting is available. Coverage is also available for treatment services that are provided in the outpatient department of a hospital to patients who, for example, have been discharged from an inpatient stay for the treatment of drug substance abuse or who require treatment but do not require the availability and intensity of services found only in the inpatient hospital setting. The coverage available for these services is subject to the same rules generally applicable to the

coverage of outpatient hospital services. (See HCFA-Pub. 13-3, §§ 3112 ff.; HCFA-Pub. 10, §§ 230 ff.). The services must also be reasonable and necessary for treatment of the individual's condition. (See HCFA-Pub. 13-3, § 3151; HIM-10, § 260.1.) Decisions regarding reasonableness and necessity of treatment, the need for an inpatient hospital level of care, and length of treatment should be made by intermediaries based on accepted medical practice with the advice of their medical consultant. (In hospitals under PSRO review, PSRO determinations of medical necessity of services and appropriateness of the level of care at which services are provided are binding on the title XVIII fiscal intermediaries for purposes of adjudicating claims for payment.)

35-22.3 TREATMENT OF ALCOHOLISM AND DRUG ABUSE IN A FREESTANDING CLINIC

Coverage is available for alcoholism or drug abuse treatment services (such as drug therapy, psychotherapy, and patient education) that are provided incident to a physician's professional service in a freestanding clinic to patients who, for example, have been discharged from an inpatient hospital stay for the treatment of alcoholism or drug abuse or to individuals who are not in the acute stages of alcoholism or drug abuse but require treatment. The coverage available for these services is subject to the same rules generally applicable to the coverage of clinic services. (See HCFA-Pub. 14-3, §§ 2020 ff., and §§ 2050 ff.) Of course, the services also must be reasonable and necessary for the diagnosis or treatment of the individual's alcoholism or drug abuse. The Part B psychiatric limitation (see HCFA-Pub. 14-3, § 2470) would apply to alcoholism or drug abuse treatment services furnished by physicians to individuals who are not hospital inpatients.

35-23 CHEMICAL AVERSION THERAPY FOR TREATMENT OF ALCOHOLISM

Chemical aversion therapy is a behavior modification technique that is used in the treatment of alcoholism. Chemical aversion therapy facilitates alcohol abstinence through the development of conditioned aversions to the taste, smell, and sight of alcohol beverages. This is accomplished by repeatedly pairing alcohol with unpleasant symptoms (e.g., nausea) which have been induced by one of several chemical agents. While a number of drugs have been employed in chemical aversion therapy, the three most commonly used are emetine, apomorphine, and lithium. None of the drugs being used, however, have yet been approved by the Food and Drug Administration specifically for use in chemical aversion therapy for alcoholism. Accordingly, when these drugs are being employed in conjunction with this therapy, patients undergoing this treatment need to be kept under medical observation.

Available evidence indicates that chemical aversion therapy may be an effective component of certain alcoholism treatment programs, particularly as part of multimodality treatment programs which include other behavioral techniques and therapies, such as psychotherapy. Based on this evidence, HCFA's medical consultants have recommended that chemical aversion therapy be covered under Medicare. However, since chemical aversion therapy is a demanding therapy which may not be appropriate for all Medicare beneficiaries needing treatment for alcoholism, a physician should certify to the

appropriateness of chemical aversion therapy in the individual case. Therefore, if chemical aversion therapy for treatment of alcoholism is determined to be reasonable and necessary for an individual patient, it is covered under Medicare.

When it is medically necessary for a patient to receive chemical aversion therapy as a hospital inpatient, coverage for care in that setting is available. (See §35-22 regarding coverage of multimodality treatment programs.) Followup treatments for chemical aversion therapy can generally be provided on an outpatient basis. Thus, where a patient is admitted as an inpatient for receipt of chemical aversion therapy, there must be documentation by the physician of the need in the individual case for the inpatient hospital admission.

Decisions regarding reasonableness and necessity of treatment and the need for an inpatient hospital level of care should be made by intermediaries based on accepted medical practice with the advice of their medical consultant. (In hospitals under PSRO review, PSRO determinations of medical necessity of services and appropriateness of the level of care at which services are provided are binding on the title XVIII fiscal intermediaries for purposes of adjudicating claims for payment.)

35-23.1 ELECTRICAL AVERSION THERAPY FOR TREATMENT OF ALCOHOLISM (ELECTROVERSION THERAPY, ELECTRO-SHOCK THERAPY, NOXIOUS FARADIC STIMULATION)

Electrical aversion therapy is a behavior modification technique to foster abstinence from ingestion of alcoholic beverages by developing in a patient conditioned aversions to their taste, smell and sight through electric stimulation. Electrical aversion therapy has not been shown to be safe and effective and therefore is excluded from coverage. (See also §§ 35-22, 35-23, and 35-27).

35-24 DIAGNOSIS AND TREATMENT OF IMPOTENCE

Program payment may be made for diagnosis and treatment of sexual impotence. Impotence is a failure of a body part for which the diagnosis, and frequently the

treatment, require medical expertise. Depending on the cause of the condition, treatment may be surgical; e.g., implantation of a penile prosthesis, or nonsurgical; e.g., medical or psychotherapeutic treatment. Since causes and, therefore, appropriate treatment vary, if abuse is suspected it may be necessary to request documentation of appropriateness in individual cases. If treatment is furnished to patients (other than hospital inpatients) in connection with a mental condition, apply the psychiatric service limitation described in the Carriers Manual, §2470.

35-25 CARDIAC REHABILITATION PROGRAMS.

A. General.--Exercise programs for cardiac patients, commonly referred to as cardiac rehabilitation programs, are increasingly being conducted in specialized, free-standing, cardiac rehabilitation clinics as well as in outpatient hospital departments. Exercise programs include specific types of exercise, individually prescribed for each patient.

Medicare coverage of cardiac rehabilitation programs are considered reasonable and necessary only for patients with a clear medical need, who are referred by their attending physician and (1) have a documented diagnosis of acute myocardial infarction within the preceding 12 months; or (2) have had coronary bypass surgery; and/or (3) have stable angina pectoris.

Cardiac rehabilitation programs may be provided either by the outpatient department of a hospital or in a physician-directed clinic. Coverage for either program is subject to the following conditions:

- o The facility meets the definition of a hospital outpatient department or a physician-directed clinic, i.e., a physician is on the premises available to perform medical duties at all times the facility is open, and each patient is under the care of a hospital or clinic physician;
- o The facility has available for immediate use all the necessary cardio-pulmonary emergency diagnostic and therapeutic life saving equipment accepted by the medical community as medically necessary, e.g., oxygen, cardiopulmonary resuscitation equipment, or defibrillator;
- o The program is conducted in an area set aside for the exclusive use of the program while it is in session;
- o The program is staffed by personnel necessary to conduct the program safely and effectively, who are trained in both basic and advanced life support techniques and in exercise therapy for coronary disease. Services of nonphysician personnel must be furnished under the direct supervision of a physician. Direct supervision means that a physician must be in the exercise program area and immediately available and accessible for an emergency at all times the exercise program is conducted. It does not require that a physician be physically present in the exercise room itself, provided the contractor does not determine that the physician is too remote from the patients' exercise area to be considered immediately available and accessible. The examples below are for illustration purposes only. They are not meant to limit the discretion of the contractor to make determinations in this regard.

- The case in which a contractor determines that the presence of a physician in an office across the hall from the exercise room who is available at all times for an emergency meets the requirement that the physician is immediately available and accessible; or
- The case in which a contractor determines that the presence of a physician in a building other than that containing the exercise room does not meet the requirement that the physician is immediately available and accessible; and
 - o The nonphysician personnel are employees of either the physician, hospital, or clinic conducting the program and their services are "incident-to a physician's professional services."

Contractors need not undertake elaborate or costly monitoring activities to determine whether these requirements are met, but need only satisfy themselves to the extent that they ordinarily do in connection with, for example, the requirements for coverage of services in physician-directed clinics. (See Carriers Manual, §2050.4; Intermediary Manual, §3112.4A; Hospital Manual, §230.4.)

In addition to the conditions listed above, coverage for cardiac rehabilitation programs furnished by hospitals to outpatients are also subject to the rules described in the Intermediary Manual, §3112.4 and the Hospital Manual, §230.4. Reasonable charge reimbursement for these services which are performed in "freestanding" clinics are subject to the limitations set forth in the Carriers Manual, §5241.

B. Diagnostic Testing - Stress Testing.--A prospective candidate for a cardiac rehabilitation program must be evaluated for his suitability to participate. A valuable diagnostic test for this purpose is the stress test. The program need not necessarily include a stress test, but may accept one performed by the patient's attending physician. Stress testing performed in the outpatient department of a hospital or in a physician-directed clinic may be covered when reasonable and necessary for one or more of the following:

- o Evaluation of chest pain, especially atypical chest pain;
 - o Development of exercise prescriptions for patients with known cardiac disease;
- and/or
- o Pre and postoperative evaluation of patients undergoing coronary artery by-pass procedures.

Refer to subsection E, Utilization Screens, for the acceptable frequency of stress testing performed during an individual's exercise program.

ECG Rhythm Strips. ECG rhythm strips (and other ECG monitoring) constitute an important and necessary procedure which should be done periodically while a cardiac patient is engaged in a physician-controlled exercise program. See subsection E, Utilization Screens, for allowable screens.

C. Other Diagnostic and Therapeutic Services.--A freestanding or hospital based cardiac rehabilitation clinic may also provide diagnostic and therapeutic services other than stress testing and ECG monitoring. Any such other services must meet the usual coverage requirements for the specific service, e.g., the incident-to, and reasonable and necessary requirements.

1. Psychotherapy and Psychological Testing.--It would not normally be considered reasonable and necessary to provide psychotherapy to all cardiac rehabilitation patients, or even to test all such patients to determine whether they may have a mental, psychoneurotic, or personality disorder. However, where a patient has a diagnosed mental, psychoneurotic, or personality disorder, psychotherapy furnished by a psychiatrist--or by a psychologist rendering such services incident to a physician's professional service--may be covered. Similarly, diagnostic testing of a cardiac rehabilitation patient for a mental problem may be covered where the patient shows appropriate symptoms, e.g., excessive anxiety or fear associated with the cardiac disease.

2. Physical and Occupational Therapy.--Physical therapy and occupational therapy would not be covered when furnished in connection with cardiac rehabilitation exercise program services covered under this section unless there also is a diagnosed noncardiac condition requiring such therapy, e.g., where a patient who is just recuperating from an acute phase of heart disease may have had a stroke which would require physical and/or occupational therapy. (While the cardiac rehabilitation exercise program may by some be considered a form of physical therapy, it is a specialized program conducted and/or supervised by specially trained personnel whose services are performed under the direct supervision of a physician.) Restrictions on coverage of physical therapy and occupational therapy under this section do not affect rules regarding coverage or noncoverage of such services when furnished in a hospital inpatient or outpatient setting.

(See Intermediary Manual, §3101.9 and Hospital Manual, §210.9.)

3. Patient Education Services.--Many cardiac rehabilitation programs provide health education in the form of lectures or counseling in which patients and/or family members are given information, e.g., on diet, nutrition, and sexual activity to assist them in adjusting their living habits because of the cardiac condition. However, the same kind of information would have been furnished to a patient and/or family members by the attending physician following the patient's acute cardiac episode. Therefore, formal lectures and counseling on these subjects are not considered reasonable and necessary as a separately identifiable service when provided as a part of a cardiac rehabilitation exercise program. In addition, where a free-standing cardiac rehabilitation clinic provides board and room for the patient (and in some cases family members), these services are not covered under Medicare.

D. Duration of the Program.--Services provided in connection with a cardiac rehabilitation exercise program may be considered reasonable and necessary for up to 36 sessions, usually 3 sessions a week in a single 12 week period. Coverage for continued participation in cardiac exercise programs beyond 12 weeks would be allowed only on a case-by-case basis with exit criteria taken into consideration.

Although firm exit criteria for terminating the therapeutic outpatient exercise treatment and rehabilitation program have not been established, the following guidelines have been identified as acceptable:

- o The patient has achieved a stable level of exercise tolerance without ischemia or dysrhythmia;
- o Symptoms of angina or dyspnea are stable at the patient's maximum exercise level;
- o Patient's resting blood pressure and heart rate are within normal limits; or
- o The stress test is not positive during exercise. (A positive test in this context implies an ECG with a junctional depression of 2mm or more associated with slowly rising, horizontal, or down sloping ST segment.)

Accordingly, claims for coverage of cardiac rehabilitation exercise programs beyond 12 weeks are reviewed by the contractors' medical consultants. When claims are accompanied by acceptable documentation that the patient has not reached an exit level, coverage may be extended, but should not exceed a maximum of 24 weeks.

E. Utilization Screens.--Patients who participate in cardiac rehabilitation programs will require certain services more frequently than other patients being treated on an outpatient basis. Therefore, in order to provide coverage in a uniform manner, the following utilization screens should be implemented in addition to existing screens for any cardiac rehabilitation services not listed:

1. Group 1 Services

- o Continuous ECG telemetric monitoring during exercise;
- o ECG rhythm strip with interpretation and physician's revision of exercise prescription; and
- o Limited examination for physician followup to adjust medication or other treatment changes.

A visit including one or more of this range of routine services is considered as one routine cardiac rehabilitation visit. In order for the visit to be reimbursable, at least one of the Group 1 services must be performed. The same rate of reimbursement would be allowed for each visit, but not all the services need be performed at each visit.

Allow a maximum of three visits per week.

2. Group 2 Services

- o New patient comprehensive evaluation, including history, physical, and preparation of initial exercise prescription.

Allow one at the beginning of the program if not already performed by the patient's attending physician, or if that performed by the patient's attending physician is not acceptable to the program's director.

o ECG stress test (treadmill or bicycle ergometer) with physician monitoring and report.

Allow one at the beginning of the program and one after 3 months (usually the completion of the program).

- o Other physician services, as needed.

35-26 TREATMENT OF OBESITY

Obesity itself cannot be considered an illness. The immediate cause is a caloric intake which is persistently higher than caloric output. Program payment may not be made for treatment of obesity alone since this treatment is not reasonable and necessary for the diagnosis or treatment of an illness or injury. However, although obesity is not in itself an illness, it may be caused by illnesses such as hypothyroidism, Cushing's disease, and hypothalamic lesions. In addition, obesity can aggravate a number of cardiac and respiratory diseases as well as diabetes and hypertension. Therefore, services in connection with the treatment of obesity are covered services when such services are an integral and necessary part of a course of treatment for one of these illnesses.

Cross refer: CIM 35-33 and 35-40

35-26.1 SUPPLEMENTED FASTING

Supplemented fasting is a type of very low calorie weight reduction regimen used to achieve rapid weight loss. The reduced calorie intake is supplemented by a mixture of protein, carbohydrates, vitamins and minerals. Serious questions exist about the safety of prolonged adherence for 2 months or more to a very low calorie weight reduction regimen as a general treatment for obesity, because of instances of cardiopathology and sudden death, as well as possible loss of body protein. Therefore, supplemented fasting is not covered as a general treatment for obesity.

In cases where weight loss is necessary before surgery in order to ameliorate the complications posed by obesity when it coexists with pathological conditions such as cardiac and respiratory diseases, diabetes or hypertension (and other more conservative techniques to achieve this end are not regarded as appropriate), supplemented fasting with adequate monitoring of the patient are covered under Medicare on a case-by-case basis, as determined by your medical consultant. The risks associated with the achievement of rapid weight loss must be carefully balanced against the risk posed by the condition requiring surgical treatment.

35-27 BIOFEEDBACK THERAPY

Biofeedback therapy provides visual, auditory or other evidence of the status of certain body functions so that a person can exert voluntary control over the functions, and thereby alleviate an abnormal bodily condition. Biofeedback therapy often uses electrical devices to transform bodily signals indicative of such functions as heart rate, blood pressure, skin temperature, salivation, peripheral vasomotor activity, and gross muscle tone into a tone or light, the loudness or brightness of which shows the extent of activity in the function being measured.

Biofeedback therapy differs from electromyography, which is a diagnostic procedure used to record and study the electrical properties of skeletal muscle. An electromyography device may be used to provide feedback with certain types of biofeedback.

Biofeedback therapy is covered under Medicare only when it is reasonable and necessary for the individual patient for muscle re-education of specific muscle groups or for treating pathological muscle abnormalities of spasticity, incapacitating muscle spasm, or weakness, and more conventional treatments (heat, cold, massage, exercise, support) have not been successful. This therapy is not covered for treatment of ordinary muscle tension states or for psychosomatic conditions. (See HCFA-Pub. 14-3, §§2200ff, 2215, and 4161; HCFA-Pub. 13-3, §§3133.3, 3148, and 3149; HCFA-Pub. 10, §§242 and 242.5 for special physical therapy requirements. See also §35-20 and 65-8.)

35-29 OXYGEN TREATMENT OF INNER EAR/CARBON THERAPY (Effective for services performed on and after August 1, 1978).--NOT COVERED

Oxygen (95 percent) and carbon dioxide (5 percent) inhalation therapy for inner ear disease, such as endolymphatic hydrops and fluctuant hearing loss, is not reasonable and necessary. The therapeutic benefit deriving from this procedure is highly questionable.

35-30 BLOOD PLATELET TRANSFUSIONS

Effective for services performed on or after **August 1, 1978**, blood platelet transplants are safe and effective for the correction of thrombocytopenia and other blood defects. It is covered under Medicare when treatment is reasonable and necessary for the individual patient.

35-30.1 STEM CELL TRANSPLANTATION

Stem cell transplantation is a process in which stem cells are harvested from either a patient's or donor's bone marrow or peripheral blood for intravenous infusion. The transplant can be used to effect hematopoietic reconstitution following severely myelotoxic doses of chemotherapy (HDCT) and/or radiotherapy used to treat various malignancies. Allogeneic stem cell transplant may also be used to restore function in recipients having an inherited or acquired deficiency or defect.

A. Allogeneic Stem Cell Transplantation.--Allogeneic stem cell transplantation (ICD-9-CM procedure codes 41.02, 41.03, **41.05, and 41.08**) is a procedure in which a portion of a healthy donor's stem cell or bone marrow is obtained and prepared for intravenous infusion.

1. Covered Conditions.--The following uses of allogeneic bone marrow transplantation are covered under Medicare:

- o Effective for services performed on or after **August 1, 1978**, for the treatment of leukemia, leukemia in remission (ICD-9-CM codes 204.00 through 208.91), or aplastic anemia (ICD-9-CM codes 284.0 through 284.9) when it is reasonable and necessary; and

- o Effective for services performed on or after **June 3, 1985**, for the treatment of severe combined immunodeficiency disease (SCID) (ICD-9-CM code 279.2), and for the treatment of Wiskott - Aldrich syndrome (ICD-9-CM 279.12).

2. Noncovered Conditions.--Effective **May 24, 1996**, allogeneic stem cell transplantation is not covered as treatment for multiple myeloma (ICD-9-CM codes 203.0 and 238.6).

B. Autologous Stem Cell Transplantation (Effective for Services Performed on or After 04/28/89).--Autologous stem cell transplantation (ICD-9-CM procedure codes 41.01, 41.04, **41.07, and 41.09**) is a technique for restoring stem cells using the patient's own previously stored cells.

1. Covered Conditions.--Autologous stem cell transplantation (ICD-9-CM codes 41.01, **41.04, 41.07, 41.09**, CPT-4 code 38241) is considered reasonable and necessary under §1862(a)(1)(A) of the Act for the following conditions and is covered under Medicare for patients with:

- o Acute leukemia in remission (ICD-9-CM codes 204.01, lymphoid; 205.01, myeloid; 206.01, monocytic; 207.01, acute erythremia and erythroleukemia; and 208.01 unspecified cell type) who have a high probability of relapse and who have no human leucocyte antigens (HLA)-matched;
- o Resistant non-Hodgkin's lymphomas (ICD-9-CM codes 200.00-200.08, 200.10-200.18, 200.20-200.28, 200.80-200.88, 202.00-202.08, 202.80-202.88, and 202.90-202.98) or those presenting with poor prognostic features following an initial response;
- o Recurrent or refractory neuroblastoma (see ICD-9-CM Neoplasm by site, malignant); or
- o Advanced Hodgkin's disease (ICD-9-CM codes 201.00-201.98) who have failed conventional therapy and have no HLA-matched donor;
- o Effective **October 1, 2000**, multiple myeloma (ICD-9-CM 203.0 and 238.6) for beneficiaries less than age 78 who have Durie-Salmon stage II or III newly diagnosed or responsive multiple myeloma with adequate cardiac, renal, pulmonary and hepatic functioning. This includes those patients with previously untreated disease, those with at least a partial response to prior chemotherapy (partial response is defined as a 50% decrease *either* in measurable paraprotein [serum and/or urine] *or* in bone marrow infiltration, sustained for at least one month), and those in responsive relapse. Multiple rounds of autologous stem cell transplantation (known as tandem transplantation) will, however, remain non-covered.

2. Noncovered Conditions.--Insufficient data exist to establish definite conclusions regarding the efficacy of autologous stem cell transplantation for the following conditions:

- o Acute leukemia not in remission (ICD-9-CM codes 204.00, 205.00, 206.00, 207.00 and 208.00);
- o Chronic granulocytic leukemia (ICD-9-CM codes 205.10 and 205.11);
- o Solid tumors (other than neuroblastoma) (ICD-9-CM codes 140.0-199.1);
- o Up to **October 1, 2000**, multiple myeloma;
- o Tandem transplantation (multiple rounds of autologous stem cell transplantation) for patients with multiple myeloma;
- o Effective **October 1, 2000**, non-primary (AL) amyloidosis (ICD-9-CM 277.3);
- o Effective **October 1, 2000**, primary (AL) amyloidosis (ICD-9-CM 277.3) for Medicare beneficiaries age 64 or older.

In these cases, autologous stem cell transplantation is not considered reasonable and necessary within the meaning of §1862(a)(1)(A) of the Act and is not covered under Medicare.

35-31 TREATMENT OF DECUBITUS ULCERS

An accepted procedure for healing decubitus ulcers is to remove dead tissue from the lesions and to keep them clean to promote the growth of new tissue. This may be accomplished by hydrotherapy (whirlpool) treatments. Hydrotherapy (whirlpool) treatment for decubitus ulcers is a covered service under Medicare for patients when treatment is reasonable and necessary. Some other methods of treating decubitus ulcers, the safety and effectiveness of which have not been established, are not covered under the Medicare program. Some examples of these types of treatments are: ultraviolet light, low intensity direct current, topical application of oxygen, and topical dressings with Balsam of Peru in castor oil.

35-32 VERTEBRAL ARTERY SURGERY

Obstructions which block the flow of blood through the vertebral artery can cause vertigo, visual or speech defects, ataxia, mental confusion, or stroke. These symptoms in patients result from reduction in blood flow to the brain and range from symptoms of transient basilar ischemia to mental deterioration or completed stroke.

Five types of surgical procedures are performed to relieve obstructions to vertebral artery blood flow. They are:

- o Vertebral artery endarterectomy, a procedure which cleans out arteriosclerotic plaques which are inside the vertebral artery;
- o Vertebral artery by-pass or resection with anastomosis or graft;
- o Subclavian artery resection with or without endarterectomy;
- o Removal of laterally located osteophytes anywhere in the C6(C7)-C2 course of the vertebral artery; and
- o Arteriolysis which frees the artery from surrounding tissue, with or without arterioplexy (fixation of the vessel).

These procedures can be medically reasonable and necessary, but only if each of the following conditions is met:

- o Symptoms of vertebral artery obstruction exist;
- o Other causes have been considered and ruled out;
- o There is radiographic evidence of a valid vertebral artery obstruction; and
- o Contraindications to the procedure do not exist, such as coexistent obstructions of multiple cerebral vessels.

Angiograms documenting a valid obstruction should show not only the aortic arch with the vessels off the arch, but also show the vessels in the neck and head (providing biplane views of the carotid and vertebral vascular system). In addition, serial views are needed to diagnose "subclavian steal," the condition in which subclavian artery obstruction causes the symptoms of vertebral artery obstruction. Because the symptoms are not specific for vertebral artery obstruction, other causes must be considered. In addition to vertebral artery obstruction, the differential diagnosis should include various degenerative disorders of the brain, orthostatic hypotension, acoustic neuroma, labyrinthitis, diabetes mellitus and hypoglycemia related disorders.

Obstructions which can cause symptoms of blocked vertebral artery blood flow and which can be documented by an angiogram include:

- o Intravascular obstructions - arteriosclerotic lesions within the vertebral artery or in other arteries.
- o Extravascular obstructions -

- o Bony tissue or osteophytes, located laterally in the C6(C7)-C2 cervical vertebral area course of the vertebral artery, most commonly at C5 -C6.
- o Anatomical variations - Anomalous location of the origin of the vertebral artery, a congenital aberration, and tortuosity and kinks of the vertebral artery.
- o Fibrous tissue - Tissue changed as a result of manipulation of the neck for neck pain or injury associated with hematoma; external bands, tendinous slings, and fibrous bands.

The most controversial obstructions include vertebral artery tortuosity and kinks and connective tissue along the course of the vertebral artery, and variously called external bands, tendinous slings and fibrous bands. In the absence of symptoms of vertebral artery obstruction, vascular surgeons feel such abnormalities are insignificant. Vascular surgery experts, however, agree that these abnormalities in very rare cases do cause symptoms of vertebral artery obstruction and do necessitate surgical correction.

Vertebral artery construction and vertebral artery surgery are phrases which most physicians interpret to include only surgical cleaning (endarterectomy) and bypass (resection) procedures. However, some physicians who use these terms mean all operative manipulations which remove vertebral artery blood flow obstructions. Also, some physicians use general terms of vascular surgery, such as endarterectomy when vertebral artery related surgery is performed. Use of the above terminology specifies neither the surgical procedure performed nor its relationship to the vertebral artery. Therefore, in developing claims for this type of procedure, require specific identification of the obstruction in question and the surgical procedure performed. Also, in view of the specific coverage criteria given, develop all claims for vertebral artery surgery on a case-by-case basis.

Make payment for a surgical procedure listed above if: (1) it is reasonable and necessary for the individual patient to have the surgery performed to remove or relieve an obstruction to vertebral artery flow, and (2) the four conditions noted are met.

In all other cases, these procedures cannot be considered reasonable and necessary within the meaning of §1862(a)(1) of the Act and are not reimbursable under the program.

35-33 INTESTINAL BY-PASS SURGERY--NOT COVERED

The safety of intestinal bypass surgery for treatment of obesity has not been demonstrated. Severe adverse reactions such as steatorrhea, electrolyte depletion, liver failure, arthralgia, hypoplasia of bone marrow, and avitaminosis have sometimes occurred as a result of this procedure. It does not meet the reasonable and necessary provisions of §1862(a)(1) of the Act and is not a covered Medicare procedure.

Cross-refer: §§ 35-26, 35-40

35-34 FABRIC WRAPPING OF ABDOMINAL ANEURYSMS--NOT COVERED

Fabric wrapping of abdominal aneurysms is not a covered Medicare procedure. This is a treatment for abdominal aneurysms which involves wrapping aneurysms with cellophane or fascia lata. This procedure has not been shown to prevent eventual rupture. In extremely rare instances, external wall reinforcement may be indicated when the current accepted treatment (excision of the aneurysm and reconstruction with synthetic materials) is not a viable alternative, but external wall reinforcement is not fabric wrapping. Accordingly, fabric wrapping of abdominal aneurysms is not considered reasonable and necessary within the meaning of §1862(a)(1) of the Act.

35-35 THERAPEUTIC EMBOLIZATION
(Effective for services performed on or after April 15, 1982.)

Therapeutic embolization is covered when done for hemorrhage, and for other conditions amenable to treatment by the procedure, when reasonable and necessary for the individual patient. Renal embolization for the treatment of renal adenocarcinoma continues to be covered, effective December 15, 1978, as one type of therapeutic embolization, to:

- o Reduce tumor vascularity preoperatively;
- o Reduce tumor bulk in inoperable cases; or
- o Palliate specific symptoms.

35-37 EXTRACRANIAL-INTRACRANIAL (EC-IC) ARTERIAL BYPASS SURGERY
(Effective for services performed on or after March 27, 1991)

Extracranial-Intracranial (EC-IC) arterial bypass surgery is not a covered procedure when it is performed as a treatment for ischemic cerebrovascular disease of the carotid or middle cerebral arteries, which includes the treatment or prevention of strokes. The premise that this procedure which bypasses narrowed arterial segments improves the blood supply to the brain and reduces the risk of having a stroke has not been demonstrated to be any more effective than no surgical intervention. Accordingly, EC-IC arterial bypass surgery is not considered reasonable and necessary within the meaning of §1862(a)(1) of the Act when it is performed as a treatment for ischemic cerebrovascular disease of the carotid or middle cerebral arteries.

35-38 ULTRAFILTRATION, HEMOPERFUSION AND HEMOFILTRATION

A. Ultrafiltration.--This is a process for removing excess fluid from the blood through the dialysis membrane by means of pressure. It is not a substitute for dialysis. Ultrafiltration is utilized in cases where excess fluid cannot be removed easily during the regular course of hemodialysis. When it is performed, it is commonly done during the first hour or two of each hemodialysis on patients who, e.g., have refractory edema. Ultrafiltration is a covered procedure under the Medicare program (effective for services performed on and after 9/1/79).

Predialysis Ultrafiltration.--While this procedure requires additional staff care, the facility dialysis rate is intended to cover the full range of complicated and uncomplicated nonacute dialysis treatments. Therefore, no additional facility charge is recognized for predialysis ultrafiltration. The physician's role in ultrafiltration varies with the stability of the patient's condition. In unstable patients, the physician may need to be present at the initiation of dialysis, and available either in-house or in close proximity to monitor the patient carefully. In patients who are relatively stable, but who seem to accumulate excessive weight gain, the procedure requires only a modest increase in physician involvement over routine outpatient hemodialysis.

Occasionally, medical complications may occur which require that ultrafiltration be performed separate from the dialysis treatment, and in these cases an additional charge can be recognized. However, the claim must be documented as to why the ultrafiltration could not have been performed at the same time as the dialysis.

B. Hemoperfusion.--This is a process which removes substances from the blood using a charcoal or resin artificial kidney. When used in the treatment of life threatening drug overdose, hemoperfusion is a covered service for patients with or without renal failure (effective for services performed on and after 9/1/79). Hemoperfusion generally requires a physician to be present to initiate treatment and to be present in the hospital or an adjacent medical office during the entire procedure, as changes may be sudden. Special staff training and equipment are required.

Develop charges for hemoperfusion in the same manner as for any new or unusual service. One or two treatments are usually all that is necessary to remove the toxic compound; document additional treatments. Hemoperfusion may be performed concurrently with dialysis, and in those cases payment for the hemoperfusion reflects only the additional care rendered over and above the care given with dialysis.

The effects of using hemoperfusion to improve the results of chronic hemodialysis are not known. Therefore, hemoperfusion is not a covered service when used to improve the results of hemodialysis. In addition, it has not been demonstrated that the use of hemoperfusion in conjunction with deferoxamine (DFO), in treating symptomatic patients with iron overload, is efficacious. There is also a paucity of data regarding its efficacy in treating asymptomatic patients with iron overload. Therefore, hemoperfusion used in conjunction with DFO in treating patients with iron overload is not a covered service; i.e., it is not considered reasonable and necessary within the meaning of §1862(a)(1) of the Act.

However, the use of hemoperfusion in conjunction with DFO for the treatment of patients with aluminum toxicity has been demonstrated to be clinically efficacious and is therefore regarded as a covered service.

C. Hemofiltration--This is a process which removes fluid, electrolytes and other low molecular weight toxic substances from the blood by filtration through hollow artificial membranes and may be routinely performed in 3 weekly sessions. Hemofiltration (which is also known as diafiltration) is a covered procedure under Medicare and is a safe and effective technique for the treatment of ESRD patients and an alternative to peritoneal dialysis and hemodialysis (effective for services performed on and after August 20, 1987). In contrast to both hemodialysis and peritoneal dialysis treatments, which eliminate dissolved substances via diffusion across semipermeable membranes, hemofiltration mimics the filtration process of the normal kidney. The technique requires an arteriovenous access. Hemofiltration may be performed either in facility or at home.

The procedure is most advantageous when applied to high-risk unstable patients, such as older patients with cardiovascular diseases or diabetes, because there are fewer side effects such as hypotension, hypertension or volume overload.

35-39 INTRAOCULAR PHOTOGRAPHY (Effective for Services Furnished on or After September 1, 1979)

Intraocular photography is covered when used for the diagnosis of such conditions as macular degeneration, retinal neoplasms, choroid disturbances and diabetic retinopathy, or to identify glaucoma, multiple sclerosis and other central nervous system abnormalities. Make Medicare payment for the use of this procedure by an ophthalmologist in these situations when it is reasonable and necessary for the individual patient to receive these services.

35-40 GASTRIC BYPASS SURGERY FOR OBESITY (Effective for Services Performed on and After October 1, 1979)

Gastric bypass surgery, which is a variation of the gastrojejunostomy, is performed for patients with extreme obesity. Gastric bypass surgery for extreme obesity is

covered under the program if (1) it is medically appropriate for the individual to have such surgery; and (2) the surgery is to correct an illness which caused the obesity or was aggravated by the obesity.

Cross-refer: §§ 35-26, 35-33

35-41 DIATHERMY TREATMENT

High energy pulsed wave diathermy machines have been found to produce some degree of therapeutic benefit for essentially the same conditions and to the same extent as standard diathermy.

Accordingly, where the contractor's medical staff has determined that the pulsed wave diathermy apparatus used is one which is considered therapeutically effective, the treatments are considered a covered service, but only for those conditions for which standard diathermy is medically indicated and only when rendered by a physician or incident to a physician's professional services. Further, when the charge for covered pulsed wave diathermy treatment is substantially in excess of that which is reasonable for standard diathermy, payment is based on the reasonable charge for standard diathermy (CPT-4 code 97024, ICD-9-CM code 93.34).

Cross-refer: §35-3

35-42 WITHDRAWAL TREATMENTS FOR NARCOTIC ADDICTIONS

Withdrawal is an accepted treatment for narcotic addiction, and Part B payment can be made for these services if they are provided by the physician directly or under his personal supervision and if they are reasonable and necessary. In reviewing claims, reasonableness and necessity are determined with the aid of the contractor's medical staff.

Drugs that the physician provides in connection with this treatment are also covered if they cannot be self-administered and meet all other statutory requirements.

Cross-refer: Intermediary Manual, §3112.4B; Carriers Manual, §2050.5.

35-44 USE OF VISUAL TESTS PRIOR TO AND GENERAL ANESTHESIA DURING CATARACT SURGERY

A. Pre-Surgery Evaluations (Effective for Services Performed On or After 09-14-88).-- Cataract surgery with an intraocular lens (IOL) implant is a high volume Medicare procedure. Along with the surgery, a substantial number of preoperative tests are available to the surgeon. In most cases, a comprehensive eye examination (ocular history and ocular examination) and a single scan to determine the appropriate pseudophakic power of the IOL are sufficient. In most cases involving a simple cataract, a diagnostic ultrasound A-scan is used. For patients with a dense cataract, an ultrasound B-scan may be used.

Accordingly, where the only diagnosis is cataract(s), Medicare does not routinely cover testing other than one comprehensive eye examination (or a combination of a brief/intermediate examination not to exceed the charge of a comprehensive examination) and an A-scan or, if medically justified, a B-scan. Claims for additional tests are denied as not reasonable and necessary unless there is an additional diagnosis and the medical need for the additional tests is fully documented.

Because cataract surgery is an elective procedure, the patient may decide not to have the surgery until later, or to have the surgery performed by a physician other than the diagnosing physician. In these situations, it may be medically appropriate for the operating physician to conduct another examination. To the extent the additional tests are considered reasonable and necessary by the carrier's medical staff, they are covered.

B. General Anesthesia.--The use of general anesthesia in cataract surgery may be considered reasonable and necessary if, for particular medical indications, it is the accepted procedure among ophthalmologists in the local community to use general anesthesia. In the claims review process, do not "front-end" reject any claims for the use of general anesthesia in cataract surgery. Obtain advice from your medical consultants before deciding whether to deny a claim involving use of general anesthesia in cataract surgery. Where regular postpayment review discloses a questionable utilization pattern, obtain case documentation.

35-45 **CARDIAC CATHETERIZATION PERFORMED IN OTHER THAN A HOSPITAL SETTING** (Effective for services performed on or after 08/01/79.)

Cardiac catheterization performed in a hospital setting for either inpatients or outpatients is a covered service. The procedure may also be covered when performed in a freestanding clinic when the carrier, in consultation with the appropriate Peer Review Organization (PRO), determines that the procedure can be performed safely in all respects in the particular facility. Prior to approving Medicare payment for cardiac catheterizations performed in freestanding clinics, carriers must request PRO review of the clinic.

35-46 **ASSESSING PATIENT'S SUITABILITY FOR ELECTRICAL NERVE STIMULATION THERAPY**

Electrical nerve stimulation is an accepted modality for assessing a patient's suitability for ongoing treatment with a transcutaneous or an implanted nerve stimulator. Accordingly, program payment may be made for the following techniques when used to determine the potential therapeutic usefulness of an electrical nerve stimulator:

A. Transcutaneous Electrical Nerve Stimulation (TENS).--This technique involves attachment of a transcutaneous nerve stimulator to the surface of the skin over the peripheral nerve to be stimulated. It is used by the patient on a trial basis and its effectiveness in modulating pain is monitored by the physician, or physical therapist. Generally, the physician or physical therapist is able to determine whether the patient is likely to derive a significant therapeutic benefit from continuous use of a transcutaneous stimulator within a trial period of 1 month; in a few cases this determination may take longer to make. Document the medical necessity for such services which are furnished beyond the first month. (See §45-25 for an explanation of coverage of medically necessary supplies for the effective use of TENS.)

If TENS significantly alleviates pain, it may be considered as primary treatment; if it produces no relief or greater discomfort than the original pain electrical nerve stimulation therapy is ruled out.

However, where TENS produces incomplete relief, further evaluation with percutaneous electrical nerve stimulation may be considered to determine whether an implanted peripheral nerve stimulator would provide significant relief from pain. (See §35-46B.)

Usually, the physician or physical therapist providing the services will furnish the equipment necessary for assessment. Where the physician or physical therapist advises the patient to rent the TENS from a supplier during the trial period rather than supplying it himself/herself, program payment may be made for rental of the TENS as well as for the services of the physician or physical therapist who is evaluating its use. However, the combined program payment which is made for the physician's or physical therapist's services and the rental of the stimulator from a supplier should not exceed the amount which would be payable for the total service, including the stimulator, furnished by the physician or physical therapist alone.

B. Percutaneous Electrical Nerve Stimulation (PENS).--This diagnostic procedure which involves stimulation of peripheral nerves by a needle electrode inserted through the skin is performed only in a physician's office, clinic, or hospital outpatient department. Therefore, it is covered only when performed by a physician or incident to physician's service. If pain is effectively controlled by percutaneous stimulation, implantation of electrodes is warranted.

As in the case of TENS (described in subsection A), generally the physician should be able to determine whether the patient is likely to derive a significant therapeutic benefit from continuing use of an implanted nerve stimulator within a trial period of 1 month. In a few cases, this determination may take longer to make. The medical necessity for such diagnostic services which are furnished beyond the first month must be documented.

NOTE: Electrical nerve stimulators do not prevent pain but only alleviate pain as it occurs. A patient can be taught how to employ the stimulator, and once this is done, can use it safely and effectively without direct physician supervision. Consequently, it is inappropriate for a patient to visit his/her physician, physical therapist, or an outpatient clinic on a continuing basis for treatment of pain with electrical nerve stimulation. Once it is determined that electrical nerve stimulation should be continued as therapy and the patient has been trained to use the stimulator, it is expected that a stimulator will be implanted or the patient will employ the TENS on a continual basis in his/her home. Electrical nerve stimulation treatments furnished by a physician in his/her office, by a physical therapist or outpatient clinic are excluded from coverage by §1862(a)(1) of the Act. (See §65-8 for an explanation of coverage of the therapeutic use of implanted peripheral nerve stimulators under the prosthetic devices benefit. See §60-20 for an explanation of coverage of the therapeutic use of TENS under the durable medical equipment benefit.)

35-47 BREAST RECONSTRUCTION FOLLOWING MASTECTOMY (Effective for services performed on and after May 15, 1980.)

During recent years, there has been a considerable change in the treatment of diseases of the breast such as fibrocystic disease and cancer. While extirpation of the disease remains of primary importance, the quality of life following initial treatment is increasingly recognized as of great concern. The increased use of breast reconstruction procedures is due to several factors:

- o A change in epidemiology of breast cancer, including an apparent increase in incidence;
- o Improved surgical skills and techniques;
- o The continuing development of better prostheses; and
- o Increasing awareness by physicians of the importance of postsurgical psychological adjustment.

Reconstruction of the affected and the contralateral unaffected breast following a medically necessary mastectomy is considered a relatively safe and effective noncosmetic procedure. Accordingly, program payment may be made for breast reconstruction surgery following removal of a breast for any medical reason.

Program payment may not be made for breast reconstruction for cosmetic reasons. (Cosmetic surgery is excluded from coverage under §1862(a)(10) of the Social Security Act.)

| 35-48 OSTEOGENIC STIMULATION

Electrical stimulation to augment bone repair can be attained either invasively or noninvasively. Invasive devices provide electrical stimulation directly at the fracture site either through percutaneously placed cathodes or by implantation of a coiled cathode wire into the fracture site. The power pack for the latter device is implanted into soft tissue near the fracture site and subcutaneously connected to the cathode, creating a self-contained system with no external components. The power supply for the former device is externally placed and the leads connected to the inserted cathodes. With the noninvasive device, opposing pads, wired to an external power supply, are placed over the cast. An electromagnetic field is created between the pads at the fracture site.

1. Noninvasive Stimulator.--The noninvasive stimulator device is covered only for the following indications:

- o Nonunion of long bone fractures;
- o Failed fusion, where a minimum of nine months has elapsed since the last surgery;
- o Congenital pseudarthroses; and
- o As an adjunct to spinal fusion surgery for patients at high risk of pseudarthrosis due to previously failed spinal fusion at the same site or for those undergoing multiple level fusion. A multiple level fusion involves 3 or more vertebrae (e.g., L3-L5, L4-S1, etc).

2. Invasive (Implantable) Stimulator.--The invasive stimulator device is covered only for the following indications:

- o Nonunion of long bone fractures; and
- o As an adjunct to spinal fusion surgery for patients at high risk of pseudarthrosis due to previously failed spinal fusion at the same site or for those undergoing multiple level fusion. A multiple level fusion involves 3 or more vertebrae (e.g., L3-L5, L4-S1, etc).

Effective for services performed on or after September 15, 1980, nonunion of long bone fractures, for both noninvasive and invasive devices, is considered to exist only after 6 or more months have elapsed without healing of the fracture.

Effective for services performed on or after April 1, 2000, nonunion of long bone fractures, for both noninvasive and invasive devices, is considered to exist only when serial radiographs have confirmed that fracture healing has ceased for three or more months prior to starting treatment with the electrical osteogenic stimulator. Serial radiographs must include a minimum of two sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days.

B. Ultrasonic Osteogenic Stimulators.--An ultrasonic osteogenic stimulator is a non-invasive device that emits low intensity, pulsed ultrasound. The ultrasound signal is applied to the skin surface at the fracture location via ultrasound, conductive gel in order to stimulate fracture healing.

Effective for services performed on or after January 1, 2001, ultrasonic osteogenic stimulators are covered as medically reasonable and necessary for the treatment of non-union fractures. In demonstrating nonunion of fractures, we would expect :

1. A minimum of two sets of radiographs obtained prior to starting treatment with the osteogenic stimulator, separated by a minimum of 90 days. Each radiograph must include multiple views of the fracture site accompanied with a written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the two sets of radiographs.

2. Indications that the patient failed at least one surgical intervention for the treatment of the fracture.

Non-unions of the skull, vertebrae, and those that are tumor-related are excluded from coverage. The ultrasonic osteogenic stimulator may not be used concurrently with other non-invasive osteogenic devices. The national non-coverage policy related to ultrasonic osteogenic stimulators for fresh fractures and delayed unions remains in place. This policy relates only to non-union as defined above.

35-49 HYPERTHERMIA FOR TREATMENT OF CANCER (Effective for services performed on or after December 31, 1984.)

Local hyperthermia for treatment of cancer consists of the use of heat to make tumors more susceptible to cancer therapy measures.

Local hyperthermia is covered under Medicare when used in connection with radiation therapy for the treatment of primary or metastatic cutaneous or subcutaneous superficial malignancies. It is not covered when used alone or in connection with chemotherapy.

35-50 COCHLEOSTOMY WITH NEUROVASCULAR TRANSPLANT FOR MENIERE'S DISEASE - NOT COVERED

Meniere's disease (or syndrome) is a common cause of paroxysmal vertigo. Meniere's syndrome is usually treated medically. When medical treatment fails, surgical treatment may be required.

While there are two recognized surgical procedures used in treating Meniere's disease (decompression of the endolymphatic hydrops and labyrinthectomy), there is no scientific evidence supporting the safety and effectiveness of cochleostomy with neurovascular transplant in treatment of Meniere's syndrome. Accordingly, Medicare does not cover cochleostomy with neurovascular transplant for treatment of Meniere's disease.

35-51 HEMODIALYSIS FOR TREATMENT OF SCHIZOPHRENIA - NOT COVERED

Scientific evidence supporting use of hemodialysis as a safe and effective means of treatment for schizophrenia is inconclusive at this time. Accordingly, Medicare does not cover hemodialysis for treatment of schizophrenia.

35-52 LASER PROCEDURES

Medicare recognizes the use of lasers for many medical indications. Procedures performed with lasers are sometimes used in place of more conventional techniques. In the absence of a specific noncoverage instruction, and where a laser has been approved for marketing by the Food and Drug Administration, contractor discretion may be used to determine whether a procedure performed with a laser is reasonable and necessary and, therefore, covered.

The determination of coverage for a procedure performed using a laser is made on the basis that the use of lasers to alter, revise, or destroy tissue is a surgical procedure. Therefore, coverage of laser procedures is restricted to practitioners with training in the surgical management of the disease or condition being treated.

35-53 ADULT LIVER TRANSPLANTATION

A. General.--Effective July 15, 1996, adult liver transplantation when performed on beneficiaries with end stage liver disease other than hepatitis B or malignancies is covered under Medicare when performed in a facility which is approved by HCFA as meeting institutional coverage criteria.

Effective December 10, 1999, adult liver transplantation when performed on beneficiaries with end stage liver disease other than malignancies is covered under Medicare when performed in a facility which is approved by HCFA as meeting institutional coverage criteria.

Coverage of adult liver transplantation is effective as of the date of the facility's approval, but for applications received before July 13, 1991, can be effective as early as March 8, 1990. (See ***Federal Register*** 56 FR 15006 dated April 12, 1991.)

B. Follow-up Care.--Follow-up care or retransplantation (ICD-9-CM 996.82, Complications of Transplanted Organ, Liver) required as a result of a covered liver transplant is covered, provided such services are otherwise reasonable and necessary. Follow-up care is also covered for patients who have been discharged from a hospital after receiving a noncovered liver transplant. Coverage for follow-up care is for items and services that are reasonable and necessary as determined by Medicare guidelines. (See Intermediary Manual, §3101.14 and Carriers Manual, §2300.1.)

C. Immunosuppressive Drugs.--See Intermediary Manual, §3660.8 and Carriers Manual, §§2050.5, 4471, and 5249.

35-53.1 PEDIATRIC LIVER TRANSPLANTATION

Effective for services performed on or after February 9, 1984, liver transplantation is covered for children (under age 18) with extrahepatic biliary atresia or any other form of end stage liver disease, except that coverage is not provided for children with a malignancy extending beyond the margins of the liver or those with persistent viremia.

Effective for services performed on or after April 12, 1991, liver transplantation is covered for Medicare beneficiaries when performed in a pediatric hospital that performs pediatric liver transplants if the hospital submits an application which HCFA approves documenting that:

- o The hospital's pediatric liver transplant program is operated jointly by the hospital and

another facility that has been found by HCFA to meet the institutional coverage criteria in the *Federal Register* notice of April 12, 1991;

- o The unified program shares the same transplant surgeons and quality assurance program (including oversight committee, patient protocol, and patient selection criteria); and

- o The hospital is able to provide the specialized facilities, services, and personnel that are required by pediatric liver transplant patients.

35-54 REFRACTIVE KERATOPLASTY- NOT COVERED

Refractive keratoplasty is surgery to reshape the cornea of the eye to correct vision problems such as myopia (nearsightedness) and hyperopia (farsightedness). Refractive keratoplasty procedures include keratomileusis, in which the front of the cornea is removed, frozen, reshaped, and stitched back on the eye to correct either near or farsightedness; keratophakia, in which a reshaped donor cornea is inserted in the eye to correct farsightedness; and radial keratotomy, in which spoke-like slits are cut in the cornea to weaken and flatten the normally curved central portion to correct nearsightedness.

The correction of common refractive errors by eyeglasses, contact lenses or other prosthetic devices is specifically excluded from coverage. The use of radial keratotomy and/or keratoplasty for the purpose of refractive error compensation is considered a substitute or alternative to eye glasses or contact lenses, which are specifically excluded by §1862 (a)(7) of the Act (except in certain cases in connection with cataract surgery). In addition, many in the medical community consider such procedures cosmetic surgery, which is excluded by section §1862 (a)(10) of the Act. Therefore, radial keratotomy and keratoplasty to treat refractive defects are not covered.

Keratoplasty that treats specific lesions of the cornea, such as phototherapeutic keratectomy that removes scar tissue from the visual field, deals with an abnormality of the eye and is not cosmetic surgery. Such cases may be covered under §1862(a)(1)(A) of the Act.

The use of lasers to treat ophthalmic disease constitutes ophthalmologic surgery. Coverage is restricted to practitioners who have completed an approved training program in ophthalmologic surgery.

35-55 TRANSVENOUS (CATHETER) PULMONARY EMBOLICTOMY - NOT COVERED

Transvenous (catheter) pulmonary embolectomy is a procedure for removing pulmonary emboli by passing a catheter through the femoral vein. It is not covered under Medicare because it is still experimental.

35-56 FLUIDIZED THERAPY DRY HEAT FOR CERTAIN MUSCULOSKELETAL DISORDERS

Fluidized therapy is a high intensity heat modality consisting of a dry whirlpool of finely divided solid particles suspended in a heated air stream, the mixture having the properties of a liquid. Use of fluidized therapy dry heat is covered as an acceptable alternative to other heat therapy modalities in the treatment of acute or subacute traumatic or nontraumatic musculoskeletal disorders of the extremities.

35-57 ELECTROENCEPHALOGRAPHIC MONITORING DURING SURGICAL PROCEDURES INVOLVING THE CEREBRAL VASCULATURE

Electroencephalographic (EEG) monitoring is a safe and reliable technique for the assessment of gross cerebral blood flow during general anesthesia and is covered under Medicare. Very characteristic changes in the EEG occur when cerebral perfusion is inadequate for cerebral function.

EEG monitoring as an indirect measure of cerebral perfusion requires the expertise of an

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electroencephalographer, a neurologist trained in EEG, or an advanced EEG technician for its proper interpretation.

The EEG monitoring may be covered routinely in carotid endarterectomies and in other neurological procedures where cerebral perfusion could be reduced. Such other procedures might include aneurysm surgery where hypotensive anesthesia is used or other cerebral vascular procedures where cerebral blood flow may be interrupted.

35-57.1 ELECTROENCEPHALOGRAPHIC (EEG) MONITORING DURING OPEN-HEART SURGERY - NOT COVERED

The value of EEG monitoring during open heart surgery and in the immediate post-operative period is debatable because there are little published data based on well designed studies regarding its clinical effectiveness. The procedure is not frequently used and does not enjoy widespread acceptance of benefit.

Accordingly, Medicare does not cover EEG monitoring during open heart surgery and during the immediate post-operative period.

35-58 THORACIC DUCT DRAINAGE (TDD) IN RENAL TRANSPLANTS

Thoracic duct drainage (TDD) is an immunosuppressive technique used in renal transplantation. This procedure, which removes lymph from kidney transplant recipients as a means of achieving suppression of the immune mechanism, is currently being used both pre-transplant and post-transplant in conjunction with more conventional immunotherapy. TDD is performed on an inpatient basis, and the inpatient stay is covered for patients admitted for treatment in advance of a kidney transplant as well as for those receiving it post-transplant.

TDD is a covered technique when furnished to a kidney transplant recipient or an individual approved to receive kidney transplantation in a hospital approved to perform kidney transplantation.

35-59 ENDOSCOPY

Endoscopy is a technique in which a long flexible tube-like instrument is inserted into the body orally or rectally, permitting visual inspection of the gastrointestinal tract. Although primarily a diagnostic tool, endoscopy includes certain therapeutic procedures such as removal of polyps, and endoscopic papillotomy, by which stones are removed from the bile duct.

Endoscopic procedures are covered when reasonable and necessary for the individual patient.

35-60 APHERESIS (THERAPEUTIC PHERESIS)

A. General.--Apheresis (also known as pheresis or therapeutic pheresis) is a medical procedure utilizing specialized equipment to remove selected blood constituents (plasma, leukocytes, platelets, or cells) from whole blood. The remainder is retransfused into the person from whom the blood was taken.

For purposes of Medicare coverage, apheresis is defined as an autologous procedure, i.e., blood is taken from the patient, processed, and returned to the patient as part of a continuous procedure (as distinguished from the procedure in which a patient donates blood preoperatively and is transfused with the donated blood at a later date).

B. Indications.--Apheresis is covered for the following indications:

- o Plasma exchange for acquired myasthenia gravis;

- o Leukapheresis in the treatment of leukemia;
- o Plasmapheresis in the treatment of primary macroglobulinemia (Waldenstrom);
- o Treatment of hyperglobulinemias, including (but not limited to) multiple myelomas, cryoglobulinemia and hyperviscosity syndromes;
- o Plasmapheresis or plasma exchange as a last resort treatment of thrombotic thrombocytopenic purpura (TTP);
- o Plasmapheresis or plasma exchange in the last resort treatment of life threatening rheumatoid vasculitis;
- o Plasma perfusion of charcoal filters for treatment of pruritis of cholestatic liver disease;
- o Plasma exchange in the treatment of Goodpasture's Syndrome;
- o Plasma exchange in the treatment of glomerulonephritis associated with antiglomerular basement membrane antibodies and advancing renal failure or pulmonary hemorrhage;
- o Treatment of chronic relapsing polyneuropathy for patients with severe or life threatening symptoms who have failed to respond to conventional therapy;
- o Treatment of life threatening scleroderma and polymyositis when the patient is unresponsive to conventional therapy;
- o Treatment of Guillain-Barre Syndrome; and
- o Treatment of last resort for life threatening systemic lupus erythematosus (SLE) when conventional therapy has failed to prevent clinical deterioration.

C. Settings--Apheresis is covered only when performed in the following settings:

- o In a hospital setting (either inpatient or outpatient). Nonphysician services furnished to hospital patients are covered and paid for as hospital services. When covered services are provided to hospital patients by an outside provider/supplier, the hospital is responsible for paying the provider/supplier for the services.
- o In a nonhospital setting, e.g., a physician directed clinic (see HCFA Pub. 14-3, §2050.4) when the following conditions are met:
 - A physician (or a number of physicians) is present to perform medical services and to respond to medical emergencies at all times during patient care hours;
 - Each patient is under the care of a physician; and
 - All nonphysician services are furnished under the direct, personal supervision of a physician.

35-61 TRANSSEXUAL SURGERY

Transsexual surgery, also known as sex reassignment surgery or intersex surgery, is the culmination of a series of procedures designed to change the anatomy of transsexuals to conform to their gender identity. Transsexuals are persons with an overwhelming desire to change anatomic sex because of their fixed conviction that they are members of the opposite sex. For the male-to-female, transsexual surgery entails castration, penectomy and vulva-vaginal construction. Surgery for the female-to-

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male transsexual consists of bilateral mastectomy, hysterectomy and salpingo-oophorectomy, which may be followed by phalloplasty and the insertion of testicular prostheses. Transsexual surgery for sex reassignment of transsexuals is controversial. Because of the lack of well controlled, long term studies of the safety and effectiveness of the surgical procedures and attendant therapies for transsexualism, the treatment is considered experimental. Moreover, there is a high rate of serious complications for these surgical procedures. For these reasons, transsexual surgery is not covered.

35-62 INVASIVE INTRACRANIAL PRESSURE MONITORING

Invasive intracranial pressure monitoring is a safe and effective therapeutic tool used to monitor intracranial pressure. It is usually used for patients suffering from head injuries, subarachnoid hemorrhage, intracerebral hemorrhage, Reye's syndrome, or posthypoxic, metabolic, and viral encephalopathies. It is usually performed in specialized intensive care units for neurosurgical and neurologic patients. It is a covered procedure when reasonable and necessary for the individual patient.

35-63 TINNITUS MASKING

A tinnitus masker is a device designed to be worn like a behind-the-ear hearing aid by persons seeking relief from tinnitus. Tinnitus is the perception of noise in the ear and/or head area. The masker produces external sounds to distract the person from the tinnitus.

By producing an external sound a few decibels above the person's audible threshold, tinnitus masking is thought to provide sufficient distraction from subjective idiopathic tinnitus to alleviate the discomfort and debilitation associated with endogenous sounds within the ear and/or head area.

Tinnitus masking is considered an experimental therapy at this time because of the lack of controlled clinical trials demonstrating effectiveness and the unstudied possibility of serious toxicity in the form of noise induced hearing loss. Therefore, it is not covered.

35-64 CHELATION THERAPY FOR TREATMENT OF ATHEROSCLEROSIS

Chelation therapy is the application of chelation techniques for the therapeutic or preventive effects of removing unwanted metal ions from the body. The application of chelation therapy using ethylenediamine-tetra-acetic acid (EDTA) for the treatment and prevention of atherosclerosis is controversial. There is no widely accepted rationale to explain the beneficial effects attributed to this therapy. Its safety is questioned and its clinical effectiveness has never been established by well designed, controlled clinical trials. It is not widely accepted and practiced by American physicians. EDTA chelation therapy for atherosclerosis is considered experimental. For these reasons, EDTA chelation therapy for the treatment or prevention of atherosclerosis is not covered.

Some practitioners refer to this therapy as chemoendarterectomy and may also show a diagnosis other than atherosclerosis, such as arteriosclerosis or calcinosis. Claims employing such variant terms should also be denied under this section.

Cross-refer: §45-20

35-65 GASTRIC FREEZING

Gastric freezing for chronic peptic ulcer disease is a non-surgical treatment which was popular about 20 years ago but now is seldom done. It has been abandoned due to a high complication rate, only temporary improvement experienced by patients, and lack of effectiveness when tested by double-blind, controlled clinical trials. Since the procedure is now considered obsolete, it is not covered.

35-66 TREATMENT OF PSORIASIS

Psoriasis is a chronic skin disease, for which several conventional methods of treatment have been recognized as covered. These include topical application of steroids or other drugs; ultraviolet light (actinotherapy); and coal tar alone or in combination with ultraviolet B light (Goeckerman treatment).

A newer treatment for psoriasis uses a psoralen derivative drug in combination with ultraviolet A light, known as PUVA. PUVA therapy is covered for treatment of intractable, disabling psoriasis, but only after the psoriasis has not responded to more conventional treatment. The contractor should document this before paying for PUVA therapy.

In addition, reimbursement for PUVA therapy should be limited to amounts paid for other types of photochemotherapy; ordinarily, payment should not be allowed for more than 30 days of treatment, unless improvement is documented.

35-67 MELODIC INTONATION THERAPY (Effective for Services Performed
On or After March 11, 1983)

Melodic intonation therapy is a technique used in language rehabilitation. Its purpose is to teach aphasic patients to produce useful phrases by intoning them in a melodic pattern with strong rhythmic support. Limited studies by a few institutions show some benefit for a small number of nonfluent aphasic patients otherwise unresponsive to conventional therapy.

Melodic intonation therapy is a covered service only for nonfluent aphasic patients unresponsive to conventional therapy, and only when the conditions for coverage of speech pathology services are met. Please refer to HCFA-Pub. 14-3, §§2200-2206.4, and 2216, HCFA-Pub. 13-3, §§3101.10A, and 3147-3148.4; or HCFA-Pub. 10 §§241-242.5 for these conditions of coverage.

35-69 IMPLANTATION OF ANTI-GASTROESOPHAGEAL REFLUX DEVICE.--(Effective for Services Performed on or After 06/22/87.)

The implantation of an anti-gastroesophageal reflux device is a surgical procedure for the treatment of gastroesophageal reflux, a condition in which the caustic contents of the stomach flow back into the esophagus. The procedure involves the implantation of this special device around the esophagus under the diaphragm and above the stomach, which is secured in place by a circumferential tie strap.

The implantation of this device may be considered reasonable and necessary in specific clinical situations where a conventional valvuloplasty procedure is contraindicated. The implantation of an anti-gastroesophageal reflux device is covered only for patients with documented severe or life threatening gastroesophageal reflux disease whose conditions have been resistant to medical treatment and who also:

- o have esophageal involvement with progressive systemic sclerosis; or
- o have foreshortening of the esophagus such that insufficient tissue exists to permit a valve reconstruction; or
- o are poor surgical risks for a valvuloplasty procedure; or
- o have failed previous attempts at surgical treatment with valvuloplasty procedures.

35-70 CLOSED-LOOP BLOOD GLUCOSE CONTROL DEVICE (CBGCD).--(Effective for Services Rendered on or After 7/1/83.)

The closed-loop blood glucose control device (CBGCD) is a hospital bedside device designed for short-term management of patients with insulin dependent diabetes mellitus (Type I). It consists of a rapid on-line glucose analyzer; a computer with a controller for the calculation and control of the infusion of either insulin or dextrose; a multi-channel infusion system; and a printer designed to record continuous glucose values and to provide cumulative totals of the substances infused. Its primary use is for the stabilization of Type I diabetics during periods of stress, such as trauma, labor and delivery, and surgery, when there are wide fluctuations in blood sugar levels. It serves to temporarily correct abnormal blood glucose levels (hyper- or hypo-glycemia) and this correction is made by infusion of either insulin or dextrose. Its use is generally limited to a 24- to 48-hour period because of potential complications; (e.g., sepsis, thromboses, and nonportability, etc.). The CBGCD requires specialized training for use and interpretation of its diagnostic and therapeutic contribution and continuous observation by specially trained medical personnel.

Use of the CBGCD is covered for short-term management of insulin dependent diabetics in crisis situations, in a hospital inpatient setting, and only under the direction of specially trained medical personnel.

35-71 NONSELECTIVE (RANDOM) TRANSFUSIONS AND LIVING--RELATED DONOR SPECIFIC TRANSFUSIONS (DST) IN KIDNEY TRANSPLANTATION.--(Effective for Services Rendered on or After 12/01/83.)

Transplant surgeons have established a definite correlation in both cadaver and living-related kidney transplantation between pretransplant transfusions of blood into the recipient and the success of graft retention.

These pretransplant transfusions are covered under Medicare without a specific limitation on the number of transfusions, subject to the normal Medicare blood deductible provisions. Where blood is given directly to the transplant patient; e.g., in the case of donor specific transfusions, the blood is considered replaced for purposes of the blood deductible provisions. (See HCFA Pub. 13-3 § 3235.4; HCFA Pub. 14-3 § 2455, and HCFA Pub. 10 § 222.3.)

35-72 ELECTROTHERAPY FOR TREATMENT OF FACIAL NERVE PARALYSIS (BELL'S Palsy).--NOT COVERED.

Electrotherapy for the treatment of facial nerve paralysis, commonly known as Bell's Palsy, is not covered under Medicare because its clinical effectiveness has not been established.

Electrotherapy for the treatment of facial nerve paralysis is the application of electrical stimulation to affected facial muscles to provide muscle innervation with the intention of preventing muscle degeneration. A device that generates an electrical current with controlled frequency, intensity, wave form and type (galvanic or faradic) is used in combination with a pad electrode and a hand applicator electrode to provide electrical stimulation.

35-73 INJECTION SCLEROTHERAPY FOR ESOPHAGEAL VARICEAL BLEEDING. (Effective for Services Performed on or After 10/29/84.)

Injection sclerotherapy is a technique involving insertion of a flexible fiberoptic endoscope into the esophagus, and the injection of a sclerosing agent or solution into the varicosities to control bleeding. This procedure is covered under Medicare.

35-74 EXTERNAL COUNTERPULSATION (ECP) FOR SEVERE ANGINA--COVERED

External counterpulsation (ECP), commonly referred to as enhanced external counterpulsation, is a non-invasive outpatient treatment for coronary artery disease refractory to medical and/or surgical therapy. Although these and similar devices are cleared by the Food and Drug Administration (FDA) for use in treating a variety of conditions, including stable or unstable angina pectoris, acute myocardial infarction and cardiogenic shock, Medicare coverage is limited to its use in patients with stable angina pectoris, since only that use has developed sufficient evidence to demonstrate its medical effectiveness. Other uses of this device and similar devices remain non-covered. In addition, the non-coverage of hydraulic versions of these types of devices remains in force.

Coverage is provided for the use of ECP for patients who have been diagnosed with disabling angina (Class III or Class IV, Canadian Cardiovascular Society Classification or equivalent classification) who, in the opinion of a cardiologist or cardiothoracic surgeon, are not readily amenable to surgical intervention, such as PTCA or cardiac bypass because: (1) their condition is inoperable, or at high risk of operative complications or post-operative failure; (2) their coronary anatomy is not readily amenable to such procedures; or (3) they have co-morbid states which create excessive risk.

A full course of therapy usually consists of 35 one-hour treatments, which may be offered once or twice daily, usually 5 days per week. The patient is placed on a treatment table where their lower **trunk and lower extremities are wrapped in a series of three compressive air cuffs which inflate and** deflate in synchronization with the patient's cardiac cycle.

During diastole the three sets of air cuffs are inflated sequentially (distal to proximal) compressing the vascular beds within the muscles of the calves, lower thighs and upper thighs. This action results in an increase in diastolic pressure, generation of retrograde arterial blood flow and an increase in venous return. The cuffs are deflated simultaneously just prior to systole, which produces a rapid drop in vascular impedance, a decrease in ventricular workload and an increase in cardiac output.

The augmented diastolic pressure and retrograde aortic flow appear to improve myocardial perfusion, while systolic unloading appears to reduce cardiac workload and oxygen requirements. The increased venous return coupled with enhanced systolic flow appears to increase cardiac output. As a result of this treatment, most patients experience increased time until onset of ischemia, increased exercise tolerance, and a reduction in the number and severity of anginal episodes. Evidence was presented that this effect lasted well beyond the immediate post-treatment phase, with patients symptom-free for several months to two years.

This procedure must be done under direct supervision of a physician.

35-75 INTRAOPERATIVE VENTRICULAR MAPPING--(Effective for services rendered on or after 10/29/84.)

Intraoperative ventricular mapping is the technique of recording cardiac electrical activity directly from the heart. The recording sites are usually identified from an anatomical grid and may consist of epicardial, intramural, and endocardial sites. A probe with electrodes is used to explore these surfaces and generate a map that displays the sequence of electrical activation. This information is used by the surgeon to locate precisely the site of an operative intervention.

The intraoperative ventricular mapping procedure is covered under Medicare only for the uses and medical conditions described below:

- o Localize accessory pathways associated with the Wolff-Parkinson-White (WPW) and other preexcitation syndromes;
- o Map the sequence of atrial and ventricular activation for drug-resistant supraventricular tachycardias;
- o Delineate the anatomical course of His bundle and/or bundle branches during corrective cardiac surgery for congenital heart diseases; and
- o Direct the surgical treatment of patients with refractory ventricular tachyarrhythmias.

35-77 NEUROMUSCULAR ELECTRICAL STIMULATION (NMES) IN THE TREATMENT OF DISUSE ATROPHY (Effective for services performed on and after 11-5-84.)

Neuromuscular electrical stimulation (NMES) involves the use of a device which transmits an electrical impulse to the skin over selected muscle groups by way of electrodes. Coverage of NMES is limited to the treatment of disuse atrophy where nerve supply to the muscle is intact, including brain, spinal cord and peripheral nerves, and other non-neurological reasons for disuse are causing atrophy. Some examples would be casting or splinting of a limb, contracture due to scarring of soft tissue as in burn lesions, and hip replacement surgery (until orthotic training begins). (See '45-25 for an explanation of coverage of medically necessary supplies for the effective use of NMES.)

35-78 DIAGNOSTIC ENDOCARDIAL ELECTRICAL STIMULATION (PACING)--(Effective for services performed on or after 12-03-84.)

Diagnostic endocardial electrical stimulation (EES), also called programmed electrical stimulation of the heart, is covered under Medicare when used for patients with severe cardiac arrhythmias.

Diagnostic endocardial electrical stimulation involves the detection and stimulation of cardiac electrical activity for the purpose of studying arrhythmias and abnormalities of the heart's conduction system. Intracardiac electrode catheters, intracardiac and extracardiac recordings and a stimulator device are required. From two to six multipolar electrode catheters are inserted percutaneously, usually through the femoral veins, and advanced to the heart under fluoroscopic control. Other venous or arterial routes may be employed as well. An intracardiac His bundle cardiogram is usually obtained during EES as are conventional electrocardiograms. No separate charge will be recognized for the His Bundle cardiogram. (See '50-3.)

EES is used to investigate the mechanisms, site of origin and pathways of cardiac arrhythmias as well as to select therapeutic approaches for their resolution. EES is also employed to identify patients at risk of sudden arrhythmic death. The principal use for EES is in the diagnosis and treatment of sustained ventricular tachycardia. However, it has also proven to be of value in the diagnosis and management of other complex arrhythmias, conduction defects, and after cardiac arrest.

35-79 ANESTHESIA IN CARDIAC PACEMAKER SURGERY (Effective for services performed on or after JULY 27, 1988.)

The use of general or monitored anesthesia during transvenous cardiac pacemaker surgery may be reasonable and necessary and therefore covered under Medicare only if adequate documentation of medical necessity is provided on a case-by-case basis. Obtain advice from your medical consultants or from appropriate specialty physicians or groups in your locality regarding the adequacy of documentation before deciding whether a particular claim should be covered.

A second type of pacemaker surgery that is sometimes performed involves the use of the thoracic method of implantation, which requires open surgery. Where the thoracic method is employed, general anesthesia is always used and should not require special medical documentation.

35-81 TREATMENT OF KIDNEY STONES

Traditional approaches for the treatment of kidney stones are the surgical technique nephrectomy (or nephrotomy) and endoscopic treatments via the urethra. In the last few years, several new approaches in the surgical management of upper urinary tract kidney stones have been developed, among them invasive and non-invasive lithotripsy techniques.

In addition to the traditional surgical/endoscopic techniques for the treatment of kidney stones, the following lithotripsy techniques are also covered for services rendered on or after March 15, 1985.

A. Extracorporeal Shock Wave Lithotripsy.--Extracorporeal Shock Wave Lithotripsy (ESWL) is a non-invasive method of treating kidney stones using a device called a lithotripter. The lithotripter uses shock waves generated outside of the body to break up upper urinary tract stones. It focuses the shock waves specifically on stones under X-ray visualization, pulverizing them by repeated shocks. ESWL is covered under Medicare for use in the treatment of upper urinary tract kidney stones.

B. Percutaneous Lithotripsy.--Percutaneous lithotripsy (or nephrolithotomy) is an invasive method of treating kidney stones by using ultrasound, electrohydraulic or mechanical lithotripsy. A probe is inserted through an incision in the skin directly over the kidney and applied to the stone. A form of lithotripsy is then used to fragment the stone. Mechanical or electrohydraulic lithotripsy may be used as an alternative or adjunct to ultrasonic lithotripsy. Percutaneous lithotripsy of kidney stones by ultrasound or by the related techniques of electrohydraulic or mechanical lithotripsy is covered under Medicare.

The following is covered for services rendered on or after January 16, 1988.

C. Transurethral Ureteroscopic Lithotripsy.--Transurethral ureteroscopic lithotripsy is a method of fragmenting and removing ureteral and renal stones through a cystoscope. The cystoscope is inserted through the urethra into the bladder. Catheters are passed through the scope into the opening where the ureters enter the bladder. Instruments passed through this opening into the ureters are used to manipulate and ultimately disintegrate stones, using either mechanical crushing, transcystoscopic electrohydraulic shock waves, ultrasound or laser. Transurethral ureteroscopic lithotripsy for the treatment of urinary tract stones of the kidney or ureter is covered under Medicare.

35-82 PANCREAS TRANSPLANTS

Pancreas transplantation is performed to induce an insulin independent, euglycemic state in diabetic patients. The procedure is generally limited to those patients with severe secondary complications of diabetes, including kidney failure. However, pancreas transplantation is sometimes performed on patients with labile diabetes and hypoglycemic unawareness.

Medicare has had a policy of not covering pancreas transplantation for many years as the safety and effectiveness of the procedure had not been demonstrated. The Office of Health Technology Assessment performed an assessment on pancreas-kidney transplantation in 1994. They found reasonable graft survival outcomes for patients receiving either simultaneous pancreas-kidney transplantation and pancreas after kidney transplantation.

Effective July 1, 1999, Medicare will cover whole organ pancreas transplantation (ICD-9-CM code 52.80, or 52.82, CPT code 48554) only when it is performed simultaneous with or after a kidney transplant (ICD-9-CM code 55.69, CPT code 50360, or 50365). If the pancreas transplant occurs after the kidney transplant, immunosuppressive therapy will begin with the date of discharge from the inpatient stay for the pancreas transplant.

Pancreas transplantation for diabetic patients who have not experienced end stage renal failure secondary to diabetes continues to be excluded from Medicare coverage. Medicare also excludes coverage of transplantation of partial pancreatic tissue or islet cells. There is not sufficient evidence at this time to support a determination that these procedures are reasonable and necessary.

35-83 24-HOUR AMBULATORY ESOPHAGEAL pH MONITORING--(Effective for services performed on or after June 11, 1985.)

Twenty-four hour ambulatory esophageal pH monitoring is a diagnostic procedure involving the placement of an indwelling electrode into the lower esophagus of a patient for the purpose of determining the presence of gastric reflux and measuring abnormal esophageal acid exposure.

Twenty-four hour ambulatory pH monitoring is covered by Medicare for patients who are suspected of having gastric reflux, but only if the patient presents diagnostic problems associated with atypical symptoms or the patient's symptoms are suggestive of reflux, but conventional tests have not confirmed the presence of reflux.

35-84 STEREOTACTIC CINGULOTOMY AS A MEANS OF PSYCHOSURGERY--NOT COVERED

Cingulotomy is a psychosurgical procedure designed to interrupt the interconnecting neuronal pathways of the brain involved in the regulation of the emotions and certain autonomic functions. The intent of psychosurgery is to modify or alter disturbances of behavior, thought content, or mood that are not responsive to other conventional modes of therapy, or for which no organic pathological cause can be demonstrated by established methods.

The operation usually involves bilateral lesions that are placed in the anterior cingulum of the brain. Electrocautery probes are stereotactically inserted through lateral burr holes in the skull. A radio frequency pulsating current is used to ablate the tissue that connects the limbic system to the frontal lobe. Two or three repeat procedures may be performed in the same patient when a satisfactory result has not been achieved with the first cingulotomy.

Stereotactic cingulotomy is not covered under Medicare because the procedure is considered to be investigational.

35-85 IMPLANTATION OF AUTOMATIC DEFIBRILLATORS

The implantable automatic defibrillator is an electronic device designed to detect and treat life-threatening tachyarrhythmias. The device consists of a pulse generator and electrodes for sensing and defibrillating. Effective for services performed on or after January 24, 1986 through July 1, 1991, the implantation of an automatic defibrillator (ICD-9 -CM codes 37.94-37.96 or CPT code 33246) is a covered service only when used as a treatment of last resort for patients who have had a documented episode of life-threatening ventricular tachyarrhythmia or cardiac arrest not associated with myocardial infarction. Patients must also be found, by electrophysiologic testing, to have an inducible tachyarrhythmia that proves unresponsive to medication or surgical therapy (or be considered unsuitable candidates for surgical therapy). It must be emphasized that unless all of the above described conditions and stipulations are met in a particular case, including the inducibility of tachyarrhythmia, etc., implantation of an automatic defibrillator may not be covered.

Effective for services performed on or after July 1, 1991, the implantation of an automatic defibrillator is a covered service for patients who have had a documented episode of life-threatening ventricular tachyarrhythmia or cardiac arrest not associated with myocardial infarction.

Effective for services performed on or after July 1, 1999, the implantation of an automatic defibrillator is also a covered service for patients with the following conditions:

1. A documented episode of cardiac arrest due to ventricular fibrillation not due to a transient or reversible cause;
2. Ventricular tachyarrhythmia, either spontaneous or induced, not due to a transient or reversible cause; or,
3. Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmias such as long QT syndrome or hypertrophic cardiomyopathy.

35-86 GASTRIC BALLOON FOR TREATMENT OF OBESITY--NOT COVERED.

The gastric balloon is a medical device developed for use as a temporary adjunct to diet and behavior modification to reduce the weight of patients who fail to lose weight with those measures alone. It is inserted into the stomach to reduce the capacity of the stomach and to affect early satiety.

The use of the gastric balloon is not covered under Medicare, since the long term safety and efficacy of the device in the treatment of obesity has not been established.

35-87 HEART TRANSPLANTS--(Effective for services rendered on or after October 17, 1986.)

A. General.--Cardiac transplantation is covered under Medicare when performed in a facility which is approved by Medicare as meeting institutional coverage criteria. (See HCFA Ruling 87-1.)

B. Exceptions.--In certain limited cases, exceptions to the criteria may be warranted if there is justification and if the facility ensures our objectives of safety and efficacy. Under no circumstances will exceptions be made for facilities whose transplant programs have been in existence for less than two years, and applications from consortia will not be approved.

Although consortium arrangements will not be approved for payment of Medicare heart transplants, consideration will be given to applications from heart transplant facilities that consist of more than one hospital where all of the following conditions exist:

- o The hospitals are under the common control or have a formal affiliation arrangement with each other under the auspices of an organization such as a university or a legally-constituted medical research institute; and

- o The hospitals share resources by routinely using the same personnel or services in their transplant programs. The sharing of resources must be supported by the submission of operative notes or other information that documents the routine use of the same personnel and services in all of the individual hospitals. At a minimum, shared resources means:

- The individual members of the transplant team, consisting of the cardiac transplant surgeons, cardiologists and pathologists, must practice in all the hospitals and it can be documented that they otherwise function as members of the transplant team; and

- The same organ procurement organization, immunology, and tissue-typing services must be used by all the hospitals; and

- o The hospitals submit, in the manner required (Kaplan-Meier method) their individual and pooled experience and survival data; and

- o The hospitals otherwise meet the remaining Medicare criteria for heart transplant facilities; that is, the criteria regarding patient selection, patient management, program commitment, etc.

C. Pediatric Hospitals.--Cardiac transplantation is covered for Medicare beneficiaries when performed in a pediatric hospital that performs pediatric heart transplants if the hospital submits an application which HCFA approves as documenting that:

- o The hospital's pediatric heart transplant program is operated jointly by the hospital and another facility that has been found by HCFA to meet the institutional coverage criteria in HCFA Ruling 87-1;

- o The unified program shares the same transplant surgeons and quality assurance program (including oversight committee, patient protocol, and patient selection criteria); and

- o The hospital is able to provide the specialized facilities, services, and personnel that are required by pediatric heart transplant patients.

D. Follow-up Care.--Follow-up care required as a result of a covered heart transplant is covered, provided such services are otherwise reasonable and necessary. Follow-up care is also covered for patients who have been discharged from a hospital after receiving a noncovered heart transplant. Coverage for follow-up care would be for items and services that are reasonable and necessary, as determined by Medicare guidelines. (See Intermediary Manual §3101.14 and Carriers Manual §2300.1.)

E. Immunosuppressive Drugs.--(See Intermediary Manual §3660.8 and Carriers Manual §§2050.5, 4471 and 5249.)

F. Artificial Hearts.--Medicare does not cover the use of artificial hearts or ventricular assist devices, either as a permanent replacement for a human heart or as a temporary life-support system until a human heart becomes available for transplant (often referred to as a "bridge to transplant"). (See §65-15.)

35-88 EXTRACORPOREAL PHOTOPHERESIS (Effective for services performed on or after April 8, 1988.)

Extracorporeal photopheresis is a treatment for cutaneous T-cell lymphoma (CTCL), a condition that is generally resistant to chemotherapy and radiotherapy. The treatment begins with the oral administration of the drug methoxsalen. The patient's blood is then passed through a device that permits exposure of the blood, while it is outside the body (extracorporeal), to ultraviolet A light. The blood is then returned to the patient.

Extracorporeal photopheresis is covered by Medicare only when used in the palliative treatment of the skin manifestations of CTCL that has not responded to other therapy.

35-89 SPEECH PATHOLOGY SERVICES FOR THE TREATMENT OF DYSPHAGIA
(Effective for services performed on and after 08/28/89)

Dysphagia is a swallowing disorder that may be due to various neurological, structural, and cognitive deficits. Dysphagia may be the result of head trauma, cerebrovascular accident, neuromuscular degenerative diseases, head and neck cancer, and encephalopathies. While dysphagia can afflict any age group, it most often appears among the elderly. Speech pathology services are covered under Medicare for the treatment of dysphagia, regardless of the presence of a communication disability.

Patients who are motivated, moderately alert, and have some degree of deglutition and swallowing functions are appropriate candidates for dysphagia therapy. Elements of the therapy program can include thermal stimulation to heighten the sensitivity of the swallowing reflex, exercises to improve oral-motor control, training in laryngeal adduction and compensatory swallowing techniques, and positioning and dietary modifications. Design all programs to ensure swallowing safety of the patient during oral feedings and maintain adequate nutrition.

Cross-refer: Intermediary Manual, §3101.10A; Carriers Manual, §2216; Hospital Manual, §210.11; Home Health Agency Manual, §205.2C.; Skilled Nursing Facility Manual, §230.3B.; Outpatient Physical Therapy and Comprehensive Outpatient Rehabilitation Facility Manual, §205.6.

35-90 EXTRACORPOREAL IMMUNOADSORPTION (ECI) USING PROTEIN A COLUMNS

Extracorporeal immunoadsorption (ECI), using Protein A columns, has been developed for the purpose of selectively removing circulating immune complexes (CIC) and immunoglobulins (IgG) from patients in whom these substances are associated with their diseases. The technique involves pumping the patient's anticoagulated venous blood through a cell separator from which 1-3 liters of plasma are collected and perfused over adsorbent columns, after which the plasma rejoins the separated, unprocessed cells and is retransfused to the patient.

For claims with dates of service on or after January 1, 2001, Medicare covers the use of Protein A columns for the treatment of ITP. In addition, Medicare will cover Protein A columns for the treatment of rheumatoid arthritis (RA) under the following conditions:

1. Patient has severe RA. Patient disease is active, having > 5 swollen joints, > 20 tender joints, and morning stiffness > 60 minutes.
2. Patient has failed an adequate course of a minimum of 3 Disease Modifying Anti-Rheumatic Drugs (DMARDs). Failure does not include intolerance.

Other uses of these columns are currently considered to be investigational and, therefore, not reasonable and necessary under the Medicare law. (See 1862(a)(1)(A) of the Act.)

35-91 LAPAROSCOPIC CHOLECYSTECTOMY (Effective for services performed on and after November 18, 1991)

Laparoscopic cholecystectomy is a covered surgical procedure in which a diseased gall bladder is removed through the use of instruments introduced via cannulae, with vision of the operative field maintained by use of a high-resolution television camera-monitor system (video laparoscope). For inpatient claims, use ICD-9-CM code 51.23, Laparoscopic cholecystectomy. For all other claims, use CPT codes 49310 for laparoscopy, surgical; cholecystectomy (any method), and 49311 for laparoscopy, surgical; cholecystectomy with cholangiography.

35-92 TRANSCENDENTAL MEDITATION - NOT COVERED

Transcendental meditation (TM) is a skill that is claimed to produce a state of rest and relaxation when practiced effectively. Typically, patients are taught TM techniques over the course of several sessions by persons trained in TM. The patient then uses the TM technique on his or her own to induce the relaxed state. Proponents of TM have urged that Medicare cover the training of patients to practice TM when it is medically prescribed as treatment for mild hypertension, as adjunctive therapy in the treatment of essential hypertension, or as the sole or adjunctive treatment of anxiety and other psychological stress-related disorders.

After review of this issue, HCFA has concluded that the evidence concerning the medical efficacy of TM is incomplete at best and does not demonstrate effectiveness and that a professional level of skill is not required for the training of patients to engage in TM.

Although many articles have been written about application of TM for patients with certain forms of hypertension and anxiety, there are no rigorous scientific studies that demonstrate the effectiveness of TM for use as an adjunct medical therapy for such conditions. Accordingly, neither TM nor the training of patients for its use are covered under the Medicare program.

35-93 LUNG VOLUME REDUCTION SURGERY (REDUCTION PNEUMOPLASTY, ALSO CALLED LUNG SHAVING OR LUNG CONTOURING) UNILATERAL OR BILATERAL BY OPEN OR THORACOSCOPIC APPROACH FOR TREATMENT OF EMPHYSEMA OR CHRONIC OBSTRUCTIVE PULMONARY DISEASE - NOT GENERALLY COVERED

Lung volume reduction surgery (LVRS) or reduction pneumoplasty, also referred to as lung shaving or lung contouring, is performed on patients with emphysema and chronic obstructive pulmonary disease (COPD) in order to allow the underlying compressed lung to expand, and thus, establish improved respiratory function. The goal of this procedure is to offer a better quality of life for patients with emphysema and COPD. In addition, LVRS may be offered as a “bridge to transplant” for patients who otherwise may not have been considered candidates for lung transplantation.

Unilateral or bilateral LVRS by open or thoracoscopic approach is not generally covered, because there is insufficient medical evidence available to base a determination that this procedure is generally safe and effective. Therefore, LVRS generally cannot be considered reasonable and necessary under §1862(a)(1)(A) of the Act in most cases.

When this policy was first established in December 1995, HCFA committed Medicare to reviewing the scientific literature as it was published in order to modify coverage policy as clinical data were developed. HCFA has reviewed data that suggest the need for a randomized clinical trial regarding the safety and effectiveness of LVRS. On April 24, 1996, the Health Care Financing Administration (HCFA) and the National Heart, Lung and Blood Institute (NHLBI) of the National Institutes of Health announced their intention to collaborate on a multi-center, randomized clinical study evaluating the effectiveness of LVRS. On December 20, 1996, HCFA and NHLBI announced the clinical centers and the data coordinating center that will be participating in the study. HCFA has determined that LVRS is reasonable and necessary when it is provided under the conditions detailed by the protocol of the HCFA/NHLBI clinical study. Therefore, Medicare will cover LVRS in those limited circumstances when it is provided to a Medicare beneficiary under the protocols established for the study. Coverage will be provided where the care is furnished in facilities that are approved as meeting the criteria established by HCFA and NHLBI for this study.

This study will consist of a registry of all patients referred to the participating clinical centers for LVRS. In addition, a subset of patients from the registry who meet specific inclusion criteria will be invited to participate in the randomized trial. All randomized patients will receive intensive medical therapy and pulmonary rehabilitation. Half will be selected randomly to undergo LVRS, which will be performed via median sternotomy or video-assisted thoracoscopy.

Medicare will provide coverage to those beneficiaries who may participate in the randomized trial for all services integral to the study and for which the Medicare statute does not prohibit. This includes tests performed to determine whether a beneficiary qualifies for randomization, LVRS, and follow-up tests that are necessary during participation in the randomized study. However, Medicare will not provide coverage for those services that are prohibited by the Act. For example, Medicare will provide coverage for pulmonary rehabilitation and pulmonary function testing, but will not provide coverage for oral steroids provided as part of a physician's service under §1862(s)(2) of the Act because they are self-administrable and thus statutorily excluded from coverage.

Payment for these services will be provided under the usual payment systems. For example, Part A services will be paid for according to the DRG system, and Part B physician services will be paid for according to the physician fee schedule.

The data from the randomized phase of the study will be analyzed and monitored continuously in order to determine any appropriate changes in Medicare coverage. These determinations will include if and how coverage will be continued.

35-94 TRANSMYOCARDIAL REVASCULARIZATION (TMR) FOR TREATMENT OF SEVERE ANGINA--COVERED (Effective for services performed on or after July 1, 1999)

Transmyocardial revascularization (TMR) is a surgical technique which uses a laser to bore holes through the myocardium of the heart in an attempt to restore perfusion to areas of the heart not being reached by diseased or clogged arteries. This technique is used as a late or last resort for relief of symptoms of severe angina in patients with ischemic heart disease not amenable to direct coronary revascularization interventions, such as angioplasty, stenting or open coronary bypass.

The precise workings of this technique are not certain. The original theory upon which the technique was based, that the open channels would result in increased perfusion of the myocardium, does not appear to be the major or only action at work. Several theories have been proposed, including partial denervation of the myocardium, or the triggering of the cascade of biological reactions which encourage increased development of blood vessels.

However, research at several facilities indicates that, despite this uncertainty, the technique does offer relief of angina symptoms for a period of time in patients for whom no other medical treatment offering relief is available. Studies indicate that both reduction in pain and reduction in hospitalizations are significant for most patients treated. Consequently, we have concluded that, for patients with severe angina (Class III or IV, Canadian Cardiovascular Society, or similar classification system) for whom all other medical therapies have been tried or evaluated and found insufficient, such therapy offers sufficient evidence of its medical effectiveness to treat the symptomatology. It is important to note that this technique does not provide for increased life expectancy, nor is it proven to affect the underlying cause of the angina. However, it appears effective in treating the symptoms of angina, and reducing hospitalizations and allowing patients to resume some of their normal activities of daily living.

We therefore cover TMR as a late or last resort for patients with severe (Canadian Cardiovascular Society classification Classes III or IV) angina (stable or unstable), which has been found refractory to standard medical therapy, including drug therapy at the maximum tolerated or maximum safe dosages. In addition, the angina symptoms must be caused by areas of the heart not amenable to surgical therapies such as percutaneous transluminal coronary angioplasty, stenting, coronary atherectomy or coronary bypass. Coverage is further limited to those uses of the laser used in performing the procedure which have been approved by the Food and Drug Administration for the purpose for which they are being used.

Patients would have to meet the following additional selection guidelines:

1. An ejection fraction of 25% or greater;
2. Have areas of viable ischemic myocardium (as demonstrated by diagnostic study) which are not capable of being revascularized by direct coronary intervention; and
3. Have been stabilized, or have had maximal efforts to stabilize acute conditions such as severe ventricular arrhythmias, decompensated congestive heart failure or acute myocardial infarction.

Coverage is limited to physicians who have been properly trained in the procedure. Providers of this service is performed must also document that all ancillary personnel, including physicians, nurses, operating room personnel and technicians, are trained in the procedure and the proper use of the equipment involved. Coverage is further limited to providers which have dedicated cardiac care units, including the diagnostic and support services necessary for care of patients undergoing this therapy. In addition, these providers must conform to the standards for laser safety set by the American National Standards Institute, ANSI Z136.3.

35-95 PARTIAL VENTRICULECTOMY (ALSO KNOWN AS VENTRICULAR REDUCTION, VENTRICULAR REMODELING, OR HEART VOLUME REDUCTION SURGERY) - NOT COVERED

Partial ventriculectomy, also known as ventricular reduction, ventricular remodeling, or heart volume reduction surgery, was developed by a Brazilian surgeon and has been performed only on a limited basis in the United States. This procedure is performed on patients with enlarged hearts due to end-stage congestive heart failure. Partial ventriculectomy involves reducing the size of an enlarged heart by excising a portion of the left ventricular wall followed by repair of the defect. It is asserted that this procedure makes the failing heart pump better by improving the efficiency of the remaining left ventricle.

Since the mortality rate is high and there are no published scientific articles or clinical studies regarding partial ventriculectomy, this procedure cannot be considered reasonable and necessary within the meaning of §1862(a)(1) of the Act. Therefore, partial ventriculectomy is not covered by Medicare.

35-96 CRYOSURGERY OF PROSTATE (Effective for services performed on or after July 1, 1999)

Cryosurgery of the prostate gland, also known as cryosurgical ablation of the prostate (CSAP), destroys prostate tissue by applying extremely cold temperatures in order to reduce the size of the prostate gland. It is safe and effective, as well as medically necessary and appropriate, as primary treatment for patients with clinically localized prostate cancer, Stages T1-T3.

The evidence is not yet sufficient to demonstrate the effectiveness of this procedure as salvage therapy for local failures after radical prostatectomy, external beam irradiation, and brachytherapy. Therefore, cryosurgery of the prostate as salvage therapy is not covered under Medicare. It is only covered as primary treatment for clinically localized prostate cancer.

35-97 VERTEBRAL AXIAL DECOMPRESSION (VAX-D) - NOT COVERED

Vertebral axial decompression is performed for symptomatic relief of pain associated with lumbar disk problems. The treatment combines pelvic and/or cervical traction connected to a special table that permits the traction application. There is insufficient scientific data to support the benefits of this technique. Therefore, VAX-D is not covered by Medicare.

35-98 ELECTROSTIMULATION IN THE TREATMENT OF WOUNDS - NOT COVERED

Electrical stimulation (ES) has been used or studied for many different applications, one of which is accelerating wound healing. The types of ES used for healing chronic venous and arterial wound and pressure ulcers are direct current (DC), alternating current (AC), pulsed current (PC), pulsed electromagnetic induction (PEMI), and spinal cord stimulation (SCS). An example of AC is transcutaneous electrical stimulation (TENS). The PEMI includes Pulsed Electromagnetic Field (PEMF) and Pulsed Electromagnetic Energy (PEE) using pulsed radio frequency energy, both of which are nonthermal i.e., they do not produce heat. Some ES use generators to create energy in the radio frequency band, delivered in megahertz (MHz). They typically deliver energy by contacting means such as coils, rather than by leads or surface electrodes.

There is insufficient evidence to determine any clinically significant differences in healing rates. Therefore, ES cannot be covered by Medicare because its effectiveness has not been adequately demonstrated.

35-99 ABORTION

Abortions are not covered Medicare procedures except:

1. If the pregnancy is the result of an act of rape or incest; or
2. In the case where a woman suffers from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself, that would, as certified by a physician, place the woman in danger of death unless an abortion is performed.

This restricted coverage applies to CPT codes 59840, 59841, 59850, 59851, 59852, 59855, 59856, 59857, and 59866.

35-100 PHOTODYNAMIC THERAPY

Photodynamic therapy is a medical procedure which involves the infusion of a photosensitive (light-activated) drug with a very specific absorption peak. This drug is chemically designed to have a unique affinity for the diseased tissue intended for treatment. Once introduced to the body, the drug accumulates and is retained in diseased tissue to a greater degree than in normal tissue. Infusion is followed by the targeted irradiation of this tissue with a non-thermal laser, calibrated to emit light at a wavelength that corresponds to the drug's absorption peak. The drug then becomes active and locally treats the diseased tissue.

Ocular photodynamic therapy (OPT)

OPT is used in the treatment of ophthalmologic diseases. Effective July 1, 2001, OPT (CPT code 67221) is only covered when used in conjunction with verteporfin (see §45-30 PHOTSENSITIVE DRUGS). For patients with age-related macular degeneration, OPT is only covered with a diagnosis of neovascular age-related macular degeneration (ICD-9-CM 362.52) with predominately classic subfoveal choroidal neovascular (CNV) lesions (where the area of classic CNV occupies $\geq 50\%$ of

the area of the entire lesion) at the initial visit as determined by a fluorescein angiogram (CPT code 92235). Subsequent follow-up visits will require a fluorescein angiogram prior to treatment. There are no requirements regarding visual acuity, lesion size, and number of retreatments.